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A comprehensive review on technology transfer

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Abstract

In the evolving corporate world, there's a growing focus on leveraging technological assets through technology transfer, a trend fueled by globalization, economic liberalization, and stronger intellectual property rights since the World Trade Organization's inception. These factors have integrated technology transfer as a critical aspect of the global business framework. However, the process of technology transfer is complex, and transferees often lack the necessary skills for effective management. While existing literature extensively covers these topics, it notably lacks practical solutions for these challenges. To bridge this gap, this paper introduces a novel "Life Cycle Approach for Planning and Implementing a Technology Transfer Project." This approach is designed to help avoid common pitfalls and address key management issues in technology transfer. The study begins by exploring the concept of technology transfer and reviews several existing models. It evaluates their pros and cons, leading to the proposition of the "Life Cycle Approach." This innovative model is intended to resolve frequent problems encountered by technology transferees, providing a structured methodology for managing technology transfer initiatives. The paper concludes with a mention of a project by the UNESCAP Asian and Pacific Centre for Transfer of Technology (APCTT), which utilizes this Life-Cycle concept. This project exemplifies the approach's practicality in enhancing the Asia-Pacific region's technology transfer capabilities, highlighting its relevance and applicability in diverse global contexts.

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INTRODUCTION

Technology Development and Transfer

Technology Transfer: It is a reasonable process that entails the transfer of a process, together with the related paperwork, and professional experience between the locations of the same manufacturer and those of different manufacturers [1].

In order to the successful transfer the following requirement should be met:

The equipment and facilities at the receiving unit (RU) and the sending unit (SU) should be comparable. From the sending unit [SU] to the receiving unit [RU], protocols, reports, specifications, crucial process parameters, and supporting data should be exchanged.

Terminology:

Any substance or combination of substances that, when ingested, becomes an active ingredient of that pharmaceutical activity and is intended to cure, prevent, or otherwise modify the structure and function of the body is known as an active pharmaceutical ingredient, or API [2].

Good Manufacturing Practices (GMP):

A part of quality assurance that ensures pharmaceutical products are consistently produced and controlled to the appropriate levels of quality for the intended uses.

Process validation:

This is the documented proof that gives a high level of assurance that a certain process will always produce a product that satisfies its specified action and quality standard.

Quality assurance or QA:

This is an umbrella term for a variety of issues that might have a single or multiple negative effects on a product's quality.It is everything that has been done to guarantee that pharmaceutical products are of the calibre needed for the purposes for which they are designed [3].

Quality control, or QC:

This procedure verifies that pharmaceutical items meet predetermined standards for identification, strength, purity, and other attributes. Setting requirements, testing, sampling, and obtaining analytical clearance are all part of it for raw materials, intermediates, packing materials, and final goods.

The systemic process of assessing, controlling, communicating, and reviewing risks to the pharmaceutical product's quality over the course of its life cycle is known as quality risk management, or QRM.

Sending unit [SU]:

Those disciplines within an organisation that are required to transfer a particular product, process, or method.

Receiving unit (RU):

The disciplines involved at the organisation where the transfer of a specific product, process, or method is anticipated [4].

Standard Operating Procedure [SOP]:

A formal, written protocol that is authorised and provides guidance on how to perform tasks that aren't always related to a particular product or material.

Technology Transfer Report:

An official record outlining the steps, standards, outcomes, and completion of a particular technology transfer initiative.

The process of demonstrating and recording that a process, procedure, or approach actually and consistently yields the desired results is known as validation.

Acceptance criteria:

Measurable parameters that indicate whether test results are acceptable.

Bracketing:

An experimental setup wherein only the extremes of, say, dosage strength, are tested.

It is assumed by the design that the extremes will accurately represent any samples that fall between them [5].

Change Control [C/C]:

A formal approach wherein trained representatives of relevant disciplines evaluate proposed or current changes that could impact a validated state is known as change control (C/C). The goal is to ascertain what has to be done to guarantee that the system is kept in a validated state.

Commissioning:

The process of adjusting, testing, and putting equipment or a system in place to make sure it satisfies all specifications, including those set forth in the user requirements specification and the capacity indicated by the developer or designer.

Commissioning occurs prior to qualification and validation.

Corrective action (C/A):

Any action required when monitoring at a crucial control point shows a loss of control.

Important:

Possessing the capacity to significantly affect the performance or quality of the product.

A critical control point [CCP]:

It is a stage at which control can be implemented and is necessary to stop, remove, or lower a risk to a level that is acceptable for pharmaceutical quality.

Drug Master File [DMF]:

The drug regulatory authority receives detailed information from a drug master file (DMF) about a particular facility, procedure, or product that is meant to be included in the application for marketing authorization [6].

Gap analysis:

Determining the essential components of a process that are present in the sending unit but absent from the receiving unit.

Inter-company transfer: A technological exchange between locations of several businesses.

In-Process Control [IPC]:

Audits made during manufacturing to monitor and maintain quality standards are known as in-process control, or IPC. To ensure that the product satisfies its specifications, the process should be adjusted as needed. One might also consider equipment or environment control to be a component of process control.

This is the process of conducting tests to make sure that the installations—such as machinery, measuring tools, utilities, and production spaces—that are utilised in a manufacturing process are suitably chosen, installed, and functional in compliance with defined standards.

Operational qualification [OQ]:

Recorded confirmation that the component or system performs as intended over all anticipated operating ranges [7].

Performance Qualification [PQ]:

Recorded confirmation that the apparatus or system performs reliably and offers repeatability within specified parameters and specifications over an extended length of time.

Qualification:

The process of demonstrating and recording that all buildings, systems, and equipment are appropriately set up, operate as intended, and produce the desired outcomes. Although qualification is frequently a component of validation (the first step), process validation is not the sum of the qualification procedures by themselves.

Spiking:

This is the process of adding a known quantity of a substance to a placebo, standard, or samples with the aim of verifying the effectiveness of an analytical technique [8].

Technology transfer [TOT]:

A methodical process that manages the transfer of an established process, along with its documentation and expert knowledge, to a location that can replicate the process and its supporting operations at a predefined degree of capability.

The validation master plan [VMP]:

This is a comprehensive document that serves as an overarching validation strategy for the entire project. It also provides an overview of the manufacturer's philosophy and methodology, which is utilised to determine whether performance is enough. It gives details on the manufacturer's validation work programme, specifies the scope of the validation work to be done, and outlines the deadlines for completion. It also outlines the roles of people carrying out the plan [9].

Methodology [or plan] for validation [VP]:

An outline of the tasks to be carried out during a validation, along with the requirements for the approval of a manufacturing process-or a part therefore for routine use.

Validation reports [VR]:

A written document that compiles and summarises the documentation, findings, and assessment of a finished validation programme. It could also include suggestions for enhancing the machinery and/or procedures.

Protocols for technology transfer [10]:

The sending and receiving units, as well as any extra agencies that may be needed, should oversee the transfer procedure and provide the necessary instructions and approvals.

For the technology transfer to be successful, there needs to be a suitable management strategy and official agreements. In accordance with the transfer protocol, the following actions must be taken. The goal and purpose of the transfer Range of the transfer. Expert staff members and their duties. Comparing the sending and receiving units' materials, tools, and techniques. Documented proof of every process control stage, as well as during pivotal moments. It should be possible to transfer the documents.

Evaluation of important control points [CCP]:

Evaluation of the manufacturing experimentation process. Evaluation of experimental processes for standardisation and analysis. Details from several batches

Method validation:

Evaluation of outcomes that are not as expected or that differ from the norm and make necessary adjustments. Examination of the final output reports of analysis that are documented. Preservation of reference materials, products with active substances, and final goods. Permission from the project manager or appropriate authorities [11].

Quality Risk Control:

A systematic approach for assessing, managing, communicating, and reviewing risks to the drug product's quality over the course of its lifecycle is called quality risk management, or QRM.

Principle:

The fundamental idea of quality control management (QRM) is to preserve product quality and customer satisfaction by assessing and evaluating associated risks using scientific knowledge and evidence.

Commencing the QRM process with the level of risk should determine the extent of work, formality, and documentation required.

Controlling Risks:

Decision-making related to risk acceptance and/or reduction is part of risk control. Reducing risk to a manageable level is the aim of risk control. Risk control might focus on the following question:

Is the risk higher than what is reasonable?

How may hazards be minimised or eliminated?

What is the right ratio of resources, risks, and benefits?

When the recognised risks are controlled, are additional risks created as a result?

Risk Reduction [12]:

Risk reduction is concerned with methods for avoiding or mitigating risks. when it surpasses a certain [acceptable] threshold of quality risk. Mitigating the degree and likelihood of harm is one way to reduce risk. A risk control strategy may also include procedures that increase the detectability of hazards and quality risks.

Risk Communication:

Risk communication is the sharing of information about hazards and risk management between decision makers and other parties. In every risk management procedure, parties are able to communicate. It is important to properly convey and document the product or outcome of the quality risk management process.

Risk Review:

It is important to put in place a system for reviewing or keeping an eye on events. New information and experience should be considered when reviewing the output and outcomes of the risk management process. The degree of risk should determine how frequently a review is conducted. Reviewing the risk acceptance decision may be part of the risk review process [6][7].

Transfer from R and D to Production [Process, packaging and cleaning]:

It is important to determine early on whether single batch manufacturing, continuous production, or campaigns are the goals, as well as whether the receiving unit can support the planned production capacity.

The degree and breadth of information to be transferred in order to support production, as well as any additional development or process optimisation at the receiving unit, as specified by the transfer project plan, should be taken into account.

In addition to creating an analogous procedure at the receiving unit, the transmitting and receiving units should work together to establish a protocol for the exchange of pertinent data on the manufacturing process under consideration [13].

Method [14]:

The sending unit provides a thorough description of the product, including its composition both qualitatively and quantitatively, physical attributes, manufacturing process, specifications for in-process control, packaging components and arrangement, and any unique safety and handling considerations. Any process development history that may be needed to allow the receiving unit to carry out any planned post-transfer process optimisation or additional development should be provided by the sending unit. The following kinds of information might be included.

Details about clinical development, such as information on the rationale for the synthesis, technology selection, equipment, route and form selection, clinical trials, and product composition.

Details or a report on large-scale development operations that includes batch counts and their disposition, as well as change and deviation controls reports that resulted in the production as it is now.

The RU should receive information from the SU regarding any health, safety, and environmental concerns related to the manufacturing processes that will be transferred, as well as any ensuing ramifications (such as the requirement for protective gear or gowning).

The procedures involved in manufacturing are described (using narrative and process maps or flow charts), along with information on in-process hold periods and conditions, the order and technique of adding raw materials, and bulk transfers between processing phases;

Analytical Method Description:

In-process controls, such as critical performance aspect identification for particular dosage forms; process control point identification; The following are examples of relevant documentation: yearly product reviews, stability data, critical processing parameter range qualification, statistical process control [SPC] charts, validation plans as well as reports, an authorised set of SOPs, and work instructions for manufacturing.

Packing:

Similar to the production transfer, it should adhere to certain procedural guidelines.

Details for an appropriate container or closure system, along with any pertinent additional information on design, packing, processing, or labelling requirements needed for qualifying packaging components at the receiving unit, are among the packaging details that need to be transferred from the sending unit to the receiving unit.

Quality Control Testing:

Drawings, artwork, and material specifications (glass, card, fibre board, etc.) should be supplied for quality control testing of packaging components.

For the purpose of preliminary packaging component qualification, the receiving unit should conduct a suitability study based on the information it has provided. When it comes to drug delivery, packaging is deemed appropriate if it offers sufficient protection against environmental factors that could degrade the drug, safety from unwanted substances released into the product, compatibility with no interactions that could affect the drug's quality, and performance [15].

Cleansing up:

Pharmaceutical items and APIs may become contaminated with one another during manufacture if distinct products are being

processed. Appropriate cleaning techniques are crucial to reduce the danger of environmental effects, operator exposure, and contamination and cross-contamination. Information on cleaning practices used at the sending unit, including details on the solubility of active ingredients, excipients, and vehicles, should be provided in order to reduce cross-contamination caused by remnants of previous manufacturing processes, exposure of operators, and environmental effects.

The TT process's granularity (including the packaging materials, final product, excipients, and API) initial supplies:

Reference batches—development batches and bio batches produced at the sending unit—should have specifications for the beginning materials [APIs and excipients] to be used at the receiving unit that match those of the reference batches. It is important to identify and characterise any qualities that could have an impact on the process or final product.

Active ingredients in pharmaceuticals (API)

The following details should be sent to the receiving unit so that it can compare the drug master file (DMF) and any pertinent additional information about the API to the API specifications:

- Manufacturer;
- Synthetic pathway flow charts illustrating the process, including raw material input points, crucial phases, process controls, and intermediates;
- The API's final form [containing photomicrographs and other pertinent data], as well as any polymorphic and solvate forms;

Degradant information, including a list of prospective and observed degradation products as well as statistics to support suggested requirements and typically observed levels [16].

Excipients [17]:

The excipients that will be employed may have an effect on the final product. Their specifications, as well as the DMF, should thus be made available by the sending unit for transfer to the receiving location. The following information should be included for all forms of excipients:

- Manufacturer
- Specification: for compendia excipients, this means monographs and other information that can impact product processing or quality; for non-compendial excipients, it means a comprehensive set of specifications that includes analytical procedures and the basis for release limitations.
- When using excipients in a human drug product for the first time or using a new mode of administration, regulatory considerations such as compendial status and appropriate regulatory information for non-compendial excipients, residual solvents or organic volatile impurities information, and documentation to support compliance with transmissible animal spongiform encephalopathy certification requirements [where applicable] are required. The same specifications apply to these as they do to pharmaceutical compounds.

Finished Products [18]:

Depending on the kind of dosage form, the transmitting unit should give the receiving unit with pertinent information on the physical qualities of excipients, such as:

- The gold standard for dose formulations that are solid and inhaled
- Solubility profile [for dose forms applied topically, inhaled, and transdermally]
- Particle distribution and size, along with measurement technique [for transdermal, inhaled, and solid dosage forms]
- Bulk physical properties [for solid and inhaled dosage forms], such as surface area, porosity, and bulk and tap densities
- Properties of compaction [for dose forms that are solid]
- The range of melting points for topical and semi-solid dosage forms
- The pH range that applies to liquid, transdermal, semi-solid/topical, and parenteral dosage forms.

Table 1 Documentation Used in Technology Transfer [TOT] [20]

Key task	Provided by SU	Transfer documentation
Project definition	Project strategy and quality plan [where applicable], protocol, risk assessments, and gap analysis.	TOT protocol for project implementation.
Quality agreement facility assessment	Facility plans and layout, building [construction, finishing] Reports on qualification status (DQ, IQ, OQ).	Comparison of receiving unit facility and buildings; gap analysis Protocol for qualification and report.
Analytical method transfer	Specifications and validation of analytical methods, including in-process quality control.	Protocol and report for the transfer of analytical methods.
Starting material evaluation equipment selection and transfer	API specifications and supplementary information, excipients inventory list of all equipment and systems, including makes, models, and qualification status [IQ, OQ, PQ]. Drawings, manuals, logs, SOPs, calibration, as well as storage].	Side-by-side comparison with receiving unit equipment [makes, models, certification status] Examine the gaps. Protocol and report for qualification and validations.
Process transfer manufacturing and packaging	Reference batches [clinical, dossier, bio-batches]Development report [manufacturing process reasoning], history of critical analytical data documenting, critical manufacturing process The drug master file. API approval status and product stability data Current master batch production and packaging records List of all batches produced Annual product assessment of deviation reports, investigations, complaints, as well as recalls.	For future reference, the receiving unit's experience, history of process development, and history should all be documented. Batch manufacturing document provisional [RU to develop] An explanation of the RU process (narrative, process map, flow graphic)Process validation guidelines and documentation.
Cleaning	Cleaning validation, solubility data, therapeutic dosages, category [toxicology], current Cleaning SOPs, chemical and micro validation reports, employed agents, and recovery research.	Cleaning SOPs unique to products and locations at RU. Protocol and report for cleaning validation

- Specific gravity (for liquid, transdermal, semi-solid/topical, and parenteral dosage types)Viscoelasticity and/or viscosity [for parenteral, semi-solid /topical, liquid, and transdermal dose forms]
- Osmolality [in the case of parenteral dose types]
- Determination of hygroscopicity and water content, including water activity data and particular handling needs [for solid and inhaled dose forms]
- Range of moisture content [for parenteral, semi-solid/topical, liquid, and transdermal dose forms]

Packaging:

The details for an appropriate container/closure system and any other pertinent data on design, packing, processing, or labelling requirements necessary for qualifying packaging components at the receiving unit are among the details that must be transferred from the sending unit to the receiving unit. Specifications for designs, artwork, and materials should be provided for quality control testing of packaging components. Table 1 shows the documentation used in technology transfer [19].

Equipment [21]

The equipment, makes, and models used in the production, filling, packing, and/or control of the good, process, or method to be transferred, as well as any current qualification and validation paperwork, should be provided by the SU. Documentation that is pertinent could comprise:

- Drawings;
- Manuals;
- Maintenance logs
- Calibration logs; and

Standard operating procedures [SOPs] (e.g., calibration, storage, cleaning, maintenance, and equipment setup). The RU should examine the data that the SU provided along with its own inventory list, which includes the qualification status (IQ, OQ, and PQ) of every piece of equipment and system. Then, in groups, the RU should compare the functionality, makes, models, and qualification status of every piece of equipment at the two sites side by side.

In order to replicate the process being transferred, the RU needs to acquire new equipment or adapt current equipment, which will need a gap analysis based on the side-by-side comparison. In addition to targeted production volumes and batch sizes (e.g., same, scaled-up, or campaign), GMP criteria should be met. Comparable factors consist of:

- Minimum and maximum capacity;
- Material of construction;
- Critical operating parameters;
- Critical equipment components [e.g., filters, screen, temperature/pressure sensors]; and
- Range of intended use.

When creating process maps or flow charts for the manufacturing process to be transferred, including employee and material movements, the location of each piece of equipment within the RU's buildings and facilities should be taken into account.

It is important to assess how producing new items may affect those now produced using the same machinery.

The transfer protocol should include a thorough development project if the current production equipment needs to be modified in order to replicate the process being transferred.

To streamline the procedure and make cleaning and maintenance tasks easier, new equipment should be planned as well as built. Any recently acquired should go through a qualification process that includes the OQ level.

By the end of OQ, appropriate operating procedures should be created for setup, use, cleaning, storage, and maintenance. Supporting documentation should be kept, including maintenance logs, calibration logs, manuals, and drawings of the equipment and pipe installations.

Verification and Qualification [22]

The completion of all crucial stages of the transfer project is contingent upon the general system, equipment, facility, as well as method validation and qualification. This will allow the RU to consistently replicate, process, or use the method in accordance with the requirements that were reached upon with the SU. A validation master plan, or VMP, should include documentation of all validation carried out during the transfer project. The validation-required phases should be identified and acceptance criteria should be defined by the VMP.

Operating under the same VMP as the SU, the RU should facilitate intra-company transfers. Prior to an inter-company transfer, the RU should have a VMP in place. For every phase in the process, the RU needs to prepare a validation procedure (VP). A validation report [VR] should provide documentation of each VP's successful execution. Validation and qualification cannot be carried out at the RU until the system has been set up and commissioned.

This guideline covers the necessary steps for buildings, services and equipment, production, packing, cleaning, and analytical testing. In a nutshell, all of these domains are covered by the same fundamental steps:

The SU should offer details on the supplies, setups, and practices used in the production of the good, service, or technique that is being transferred;

The RU should examine the data that the SU submitted and audit its present setup, tools, and

procedures, taking into account non-process related activities and support services that have an effect on the procedure;

After reviewing the material, the RU should decide whether to accept it as is or expand on it to create site-specific protocols, SOPs training programmes, and procedures that will serve as the foundation for qualification and validation. Additionally, pertinent staff members, such as operators and analysts, should receive any necessary training in new processes.

Validation of analytical test methods, process validation for manufacturing and packaging, cleaning validation, and the commissioning of necessary systems and procedures at the RU should all come after the successful training has been documented and the facility and equipment have been qualified and validated.

Reviewing the gap analysis and creating the VPs for the equipment, services, and facilities as needed are the RU's responsibilities.

The VPs related to purchase and design specifications, factory acceptance tests [FAT], IQ, and OQ, if feasible, should be met by both new and old equipment. When trial batches start, performance qualification should be established. This should include a further evaluation of operating parameters in relation to product characteristics.

A report containing the qualifying and validation processes' successful completion is required.

Quality Control [23]

All analytical testing necessary to show that the product being transferred complies with the registered specification should be accommodated by the transfer of analytical procedures. Before conducting process validation studies of manufacturing operations, the analytical method used to evaluate pharmaceutical goods, their constituents, and cleaning [residue] samples must be transferred.

Analysts and other quality control employees should receive method-specific training; When doing any RU training activities, include acceptability criteria and validation processes; helping to analyse the outcomes of quality control testing;

Identify and explain every technique that will be used to test a certain product, ingredient, or cleaning sample;

Specify acceptance criteria, sampling techniques, and experimental design;

For methods that are being transferred, provide any validation reports and show how reliable they are;

Data regarding the apparatus utilised and any standard reference samples should be provided. Give the authorised SOPs that were used during the testing. Among the duties of the RU are:

Analyse the SU's provided analytical techniques, and formally accept Criteria to be met prior to executing the transfer protocol;

Ascertain that the appropriate quality control equipment is available and qualified at the RU site. Where possible, equipment should be recreated, however it is understood that various versions, such as spectrometers and chromatographs, may already be in place. Ensure that appropriate skilled and experienced staff are available for analytical testing.

Provide a mechanism for documenting sample receipt and testing.

The Food and Drug Administration (FDA or USFDA) [24]

This government organisation is a part of the US Department of Health and Human Services, one of the country's executive departments. By regulating and overseeing the safety of food, tobacco products, nutritional supplements, pharmaceutical drugs (prescription and over-the-counter), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods and feed, as well as veterinary products, the FDA is responsible for safeguarding and advancing public health.

Technology transfer is addressed along with a few real-world examples.

Case study 1:

Table 1 presents the drug's blending with excipients. Factors taken into account in the suggested technology transfer (scale up) Similarity in Geometry: Constant fill ratio

(constant length ratio) ratio Maintaining Forces: A Dynamic Similarity (Froude number) Kinematic similarity: Keeping the number of revolutions constant.

Conclusion of case study 1:

By adjusting the aforementioned variables, such as blending time and speed, the required content homogeneity was achieved.

Drug stacking on MCC spheres:

Case Study 2 [25]

Production equipment with the highest degree of geometric similarity to the process that will be used on a commercial scale, along with particle trajectories and dynamics that are similar, allow for the maintenance of process parameters during scale-up, with the exception of air flow, which scales linearly.

Case study 2 conclusion:

To achieve a consistent drug coating on MCC spheres, the air flow rate and overall spray rate were modified. Both the pilot batch and the commercial batch had an assay of 99.9% for the formulation.

TT organisations in India: Asia-Pacific Centre for Technology Transfer (APCTT), NRDC, TIFAC, BCIL, TBSE/SIDBI [26]

It is a regional organisation of the United Nations under the auspices of the Economic and Social Commission for Asia and the Pacific (ESCAP), which was founded in Bangalore, India, in 1977. In New Delhi, India, the centre relocated.APCTT facilitates technology transfer to and from small and medium-sized enterprises (SMEs) throughout Asia and the Pacific. In order to improve the climate for technology transfer among SMEs, APCTT carries out development projects supported by foreign donors. Strengthening the region's capacity for technology transfer and facilitating the import and export of environmentally friendly technologies among its member nations are the two main goals of the APCTT.

National Research Development Corporation [NRDC]:

In pursuit of its business objectives over the last six years of its existence, NRDC has developed close ties with the scientific and industrial communities in India and outside. It is acknowledged as a vast storehouse of a wide range of technologies spanning practically all industries, including pharmaceutics, chemicals, insecticides, agriculture, and argo-processing. Biotechnology, metallurgy, construction materials, mechanical, electrical, and electronic systems, etc., It has assisted in the establishment of numerous small and medium-sized businesses and granted licences for the domestic technology to over 4800 entrepreneurs. In addition, the NRDC carries out a variety of other tasks, including value-added services, support for the advancement of technologies, awards for meritorious inventions, technological and financial aid for IPR protection, and much more.

Technology information, forecasting and assessment council [TFAC] [27][28]

TIFAC is an independent agency that was established in 1988 under the Department of Science and Technology with the goals of examining the future of technology, evaluating its trajectory, and fostering innovation through coordinated efforts in certain areas of national significance. The important responsibility of developing a technology vision for the nation in a number of new technology fields was taken on by TIFAC. APJ Abdul Kalam headed the Technology Vision 2020 project, which produced a series of 17 publications with sixteen technology-related areas and one service-related document. Throughout its more than 25 years of providing services to the country, it has produced numerous reports on technological assessments along with foresight. The Honourable Prime Minister of India, Shri Narendra Modi, unveiled the technological Roadmaps in 12 thematic areas of national importance and priority during the opening of the 103rd Indian Science Congress in Mysuru. Information and communication technology [ICT], manufacturing, education, healthcare, housing, infrastructure, and transportation.

Biotech Consortiums India Limited [BCIL]:

The Companies Act of 1956 was used to form Biotech Consortiums India Limited [BCIL], New Delhi, as a public limited company in 1990. The All India Financial Institutions and several corporate sectors provide funding for the consortium, which is supported by the Department of Biotechnology,

Government of India. Among BCIL's primary responsibilities are the department and technology transfer for biotechnology product commercialization, project consulting, biosafety awareness, and human resource development. Several important programmes and projects of the Indian government's department of biotechnology have been effectively managed by BCIL.

Technology bureau for small enterprise [TBSE]/ small industries development bank of India [SIDBI]:

The Technology Bureau for Small Enterprises (TBSE) provides MSMEs with a platform to access opportunities worldwide for the establishment or acquisition of technology. Business cooperation. The Asian and Pacific Centre for Technology Transfer (APCTT) and the Small Industries Development Bank of India (SIDBI) collaborated to create TBSE in 1995. The office of DC [SSI] also provides TBSE with a portion of its funding. Government of India. A professionally managed system for technology and cooperation exploration is one of TBSE's features that contributes to the development of trust between possible partners. By means of networking, it offers a chance to the worldwide technological market. Handling project evaluation as well as business plan creation.

TT related documentation-confidentially agreement, licensing, MoUs, legal issues. Confidentiality Agreements:

Protecting every piece of information about the parties involved in discussions is the goal of a secret agreement. All stakeholders must be able to assess the technology being offered before any serious discussions about its transfer can begin. Thus, consideration will be given to the offer's technological as well as commercial potential. A confidentiality agreement should be created before granting anyone access to your technology. It should cover all the normal elements of an agreement, such as parties, term and termination, and applicable law. A succinct but precise explanation of the technology that will be delivered should be the first item in any confidentiality agreement. What are this technology's primary features, and what is the applicable application? One can find a reference to the party offering's property rights in this same agreement disposition [29].

Licensing [30]:

A licence agreement forms the foundation of the technology transfer's legal structure. By agreeing to this, the licenser—the owner of the technology—grants the license—another company—the permission to utilise the technology. A licence does not take away the owner's property rights; he is still the exclusive owner of the technology. He might even offer his technology for sale, with the buyer acting as the owner, taking the place of the seller, with certain restricted privileges. A licence may include a licensee limitation on time, geography, product market, or application. For the term of their cooperation, the licence will define the relationship between the licenser and licensee, and many questions must be addressed before this relationship can start.

Understanding memorandums [MOUs]:

Before other agreements are carried out, collaborative research projects with external universities are frequently outlined in memoranda of understanding (MOUs). An MOU usually lays forth the parties' roles and responsibilities as well as the distribution of intellectual property. It's critical to talk about the potential for an MOU if you intend to collaborate with someone outside of your company. Memorandums of Understanding pertaining to cooperative research are drafted by the Office of Technology Commercialization.

MOUs usually designate a lead institution in charge of overseeing intellectual property and provide information about the distribution of licencing revenue.

Legal Concerns:

In technology transfer, the following categories of legal difficulties are typically seen.

Contractual laws.

Tax Implications:

Legal concerns in transactions involving intellectual property Issues pertaining to IPR litigation Indian laws protecting intellectual property.

CONCLUSION:

The study begins with a summary of technology transfer and a few key models currently in use. The models' respective advantages and disadvantages are discussed, and a unique model called "The Life Cycle Approach for Planning and Implementing a Technology Transfer Project" is offered. This methodology is expected to assist in resolving numerous frequent issues that technology transferees encounter. The study ends with a project being developed by the UNESCAP Asian and Pacific Centre for Transfer of Technology (APCTT) to support the expansion of the Asia-Pacific region's capacity for technology transfer. As the project is based on the Life-Cycle concept.

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