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# THE IMPORTANT ROLE OF TECHNOLOGY TRANSFER IN PHARMACEUTICAL INDUSTRY-A REVIEW

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### **ABSTRACT**

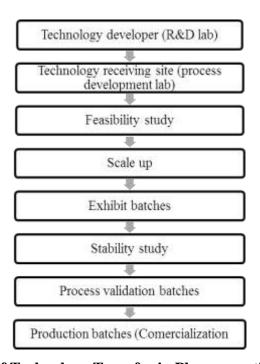
The Technology Transfer is both integral and critical to drug discovery and development process for new medicinal products this process gives necessary information for technology transfer from R&D to PDL department and development of existing product to the production for commercialization. The finishing product during manufacturing as well as assure constant quality transferred the situation for developing countries is controversial because it denied people with technical skills from developed countries to developing countries do not migrate the process of movement of technology from one unit to another. The transfer may be said to be successful if the receiving unit and the transferee can effectively utilize the technology for business gain.

Technology transfer plays a vital role in the process of drug discovery to the product development and the full scale commercialization the article attempts to discus about the pharmaceutical technology transfer process steps, reasons and importance of technology transfer and the issues involved in the technology transfer in the pharmaceutical industry. Given technology centrality to development and technology acquisition necessity by developing countries for further development and benefit it is desirable to generate transfer and diffuse the best available pharmaceutical technology in these countries through product development and scale-up technique a commercialised drug product and to highlight how technology is transferred, importance of technology transfer, rezones for technology transfer, factors influencing technology transfer, drivers and barriers. The ultimate goal for successful technology transfer is to have documented evidence that the manufacturing processes for drug substances and drug product.

**KEYWORDS:** Pharmaceutical production, Pharmaceutical technology Transfer, Management, Research and Development, Drug discovery, Exhibit batch.

### INTRODUCTION

In pharmaceutical industry Technology Transfer refers to the processes of successful progress from drug discovery to product development, clinical trials and ultimately full scale commercialization a Technology Transfer is 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. The technology transfer is both integral and critical to the drug discovery and development process for new medicinal products. Technology transfer is helpful to develop dosage form in various ways as it provides efficiency in process maintains quality of product helps to achieve standardized process which facilitates cost effective production. It is the process by which an original innovator of technology makes its technology available to commercial partner that will exploit the technology is a both integral and critical to drug discovery and development for new medicinal products. Technology Transfer is important for such research to materialise on a larger scale for commercialization especially in the case of developing product technology transfer includes not only the patentable aspects of production but also includes the business processes such as knowledge and skills. The utilization of a quality by design approach ensures a robust technology transfer form a diverse, skilled and collaborative development team a review process flow diagram for key inputs and outputs that could impact quality (QRM). The multi variant experiments should have been completed to study relationship and gain information on potential sources of variability make sure you understand your measurement capability and the change management system should provide management and documentation of adjustments made to the during technology transfer activities aspect of management review should be performed to ensure the developed product and process can be manufactured at commercial scale. The various Institute in India Assisting in Technology transfer that is Asia pacific centre for Transfer of Technology (APCTT), Technology Bureau for small enterprises (TBSE), National Research and Development corporation (NRDC) and Foundation for Innovation and Technology transfer (FITT). To exemplify specific procedure and points of concern for smooth technology transfer for the smooth manufacturing of commercialized products this is applicable to the technology transfer through R&D and production of drug chemically synthesized drug substances and drug products and the technology transfer related to post-marketing changes in manufacturing places. The ultimate goal for successful technology transfer is to have documented evidence that the manufacturing process for drug substance and drug products are robust and effective in producing the drug and drug products complying with the registered specification and good manufacturing practice requirement. Generally impact of the technology transfer program is improvement of the research pertinence and its promotion in foreign countries, contribution with the creation and consolidation of research groups and centres for technology development involving the training of young research students, promote interdisciplinary projects to be developed in the region of interest. As noted in the introduction this study focuses largely on local production and technology transfer initiatives that were not purely commercial nevertheless, even within this circumscribed set of initiatives, an important distinction emerges between technology transfer negotiated with profit making entities that is large multinational drug producers and small biotechnology companies and those supported by public whether from basic research to applied technology or from one firm to another the transfer of technology is fundamentally a matter of the flow of human knowledge from one human being to another. At least in some sectors close link between the basic researchers and the manufacturing experts and even marketing personnel contribute to competitiveness and advancement. The communicating the needs of companies to universities at technology needs communication meetings companies communicate their research related needs to universities including issues that require short term solution and issues on which companies wish to conduct collaborative research.



Flow Chart of Technology Transfer in Pharmaceutical Industry.

## **Facets of Technology Transfer**

The transfer of technology could happen in any of following ways;

- 1. The Government labs to private sector firms.
- 2. Between private sector firms of same country.
- 3. Between private sector firms of different country.
- 4. From academia to private sector firms.
- 5. Academia, industry collaborations and government.

## **Constituents of Technology Transfer**

- ➤ The Proper Work: This refer to institutional and guidelines regarding IP protection licensing modalities, which must be in place beforehand in the absences of these decision get delayed lack of fairness in decision Example case of x-institute which came up with good technology but since no guidance were there kept running around for two years and then gave up.
- The Proper Research: The proper research we mean firstly that in which the result are reproducible and issues such as scale up stability and other practical now has been addressed also that in which problem were taken up in first place.
- ➤ The Pricing: It is a most difficult and critical area of transfer of technology, too high price can put off buyer leaving the technology unsold, too price a result in revenue loss, there are basically two model regarding pricing. The price charged for a technology should depend upon market force that is impact of technology irrespective of amount spent on developing it, the price charged should include all expenses involved in developing it.
- ➤ The Publicity: It is important to identify and then approach buyer that is adopt targeted publicity and not blanket publicity Example specific journal, website, letters to manufacturers, personal selective visit etc, are some common approach which helps in locating buyer.
- ➤ The Partnership: This means working along with industry, industry takes it up, manufacturer and its makes available to society the partnership are important to ensure your technology is successfully adopted simply conveying the details may not be sufficient.
- ➤ The People's Acceptance: It is no use trying to develop a technology which people will not accept Example due to religious reason or social concern, genetically modified food, irradiated vegetables processed beef in India, improved capsule made of non-vegetarian material.

## **Goals of Technology Transfer**

The goal of technology transfer (ICH Q10) activities is to transfer product and process knowledge between development, manufacturing and within or between manufacturing sites to achieve product realisation this knowledge forms the basis for the manufacturing process, control strategy, process validation approach and ongoing continual improvement.

- It 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 on-going continuous improvement.
- The transition of the product, process, analytical method knowledge between development and manufacturing sites.
- To ensure variability of process and parameters are controlled and sufficient in the face of the rigors of a commercial production environment to verify parameters established during development are still within the determined design space and adjusted at scale-up.

## **Key Elements of Technology Transfer**

- ➤ Documentation/ Information: Consistent and controlled procedures for technology transfer and for running your process, Assurance of clear documentation of all process and product knowledge, understanding of prior knowledge from similar products.
- ➤ The Personnel: The integrated interdisciplinary team of cross functional experts like that operations, Tech operations, CMC, supply chain, analytical, Quality and R&D the roles and responsibilities of development group and the site.
- ➤ Technology Development: Assure have well understood, robust process and corresponding analytical methods, well designed and well understood equipment train the utilize principals in IHC Q8, Q9, QRM and Q10.
- The Execution: The successful manufacture of demonstration batches (This aids in site training and demonstrates that the receiving site has the ability to perform the process adequately and is the basis for process validation) understand validation requirements, strategy a continuous monitoring Example PAT, Pi Data acquisition, Proactive process analysis.
- ➤ The Pharmaceutical Quality System: Executable control strategy under the site PQS, utilize PQSs to help drive control any changes document learning during and post transfer.

## **Factors Influencing Technology Transfer**

## **Drivers of Technology Transfer**

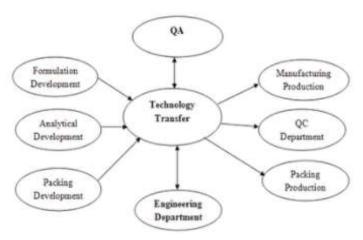
- ➤ Good business and manufacturing practices The company success is primarily the result of its adoption of good business and manufacturing practices particularly in the areas of product identification and formulation technology.
- ➤ Potential for competitive pricing The balance cost to remain competitive by having higher private sector prices and very low public sector prices.
- ➤ Strategic planning Create an enabling environment for vertical integration with prospects for higher capacity utilization and eventual lowering of production costs.
- ➤ Strong economy and environment For technology transfer to be successful there need to be supportive business and scientific environment in the recipient country and that environment should include skilled workers economic and political stability, supportive regulatory environment marketed size and potential a well developed national infrastructure of natural resources and transport.
- ➤ Opportunities for contingency supply The Multinational pharmaceuticals companies are inclined to transfer technology to local manufacturers with the potential to receive when they foresee an inability to meet time scales and volume demand from large procurers.
- ➤ Access to new machinery, training, know-how and business partnership This makes the prospect of technology transfer very desirable to local pharmaceutical manufacturers since the technology, equipment could be applied profitably beyond the initial purpose.
- ➤ Barriers of Technology Transfer Lack of efficiency, the Automation of production processes to improve efficiency and lower costs.
- ➤ Low market share The local producers face significant challenges in meeting International Quality Standards and capturing a critical market share, Greater market share would increase profitability.
- ➤ Labour issues The pharmaceutical sector demands relatively skilled labour, High labour turns over and absenteeism owing to unattractive conditions of service is negative contributor.

## Approaches to overcome barriers in Technology Transfer

➤ The Commercializing publicly funded technologies – The basic pattern envisioned is to give institutions receiving public research funds the right to obtain and exploit patents on inventions developed in the course of research.

- ➤ Research tool patents and freedom to operate for the public sector The patents sometimes make it difficult for public researchers to carry out their research or to make the products of that research available it is intensified by the tendency of some publicly funded research laboratories to avoid use of a patented technology without permission even in nations where no relevant patent is in force.
- ➤ Web access and scientific publication Limited access to scientific journals led to enormous problems for developing nations scientists.
- ➤ National security issues and restrictions on exports of particular technology International control designed to protect national security and to prevent the proliferation of important technologies also restrict the flow of technologies.
- ➤ Co-operative research agreements The global support for public sector research might be encouraged is through co-operative research agreements designed to meet specific goals it would seem more feasible to focus efforts on technologies of significant social benefit to the developing nations.
- ➤ Possible treaty on scientific access There has also been a proposal for an international treaty on access to knowledge and technology negotiated on the basis of the type of reciprocity found in normal international trade negotiations.

## **Technology Transfer Process**



- The Research Phase.
- Quality by design.
- ➤ The Development Phase.
- Research for factory production.
- Consistency between Quality and Specification.
- Assurance of consistency through development and manufacturing.

- Technology Transfer from R&D to Production.
- > The Production Phase.
- The validation and Production.
- The feedback from production and Technology Transfer of Marketed Products.

## **Steps in Technology Transfer Process**

The technology transfer is both integral and critical to the drug discovery and development process for new medicinal products. The decision to transfer products between manufacturing sites is frequently driven by economics. The key stages of the process include data collection, data review and regulatory impact with particular emphasis on any change approvals analytical validation and pilot or full-scale process batch stability set down. The technology transfer during 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 excipients availability should be taken into account during the early phases of development of formulation so that successful scale up can be carried out.

## > The Development of Technology by R&D (Research Phase).

- The Design of procedure and selection of excipients by R&D The selection of materials
  and design of procedures is developed by R&D on the basis of innovator product
  characteristics.
- The Identification of specifications and quality by R&D The Quality of product should meet the specifications of an innovator product.
- ➤ The Technology Transfer from R&D to production (Development Phase) The R&D provides technology transfer dossier (TTD) document to product development laboratory which contains all information and drug product as follows.
- The Master Formula Card (MFC) Includes product name along with its strength, generic name, MFC number, Page number, Effective date, shelf life and Market.
- The Master Packing Card (MPC) Gives information about packaging type and material used for packaging, stability profile and shelf life of packaging.
- The Master Formula It describes formulation order and manufacturing instructions that is process order and environment conditions.
- The Specifications and Standard Test Procedures (STP) Helps to know active ingredients and excipients profile in-process parameters, product release specifications and finished product details.

- **➤** The Optimization and Production (Production Phase)
- The validation studies The production is implemented after validation studies that can verify that process is able to stabilize the product based on transferred manufacturing formula, the manufacturing department accepting technology is responsible for validation and R&D department transferring technology should take responsibility for validation such as performance qualification, cleaning and process validation.
- 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 development of process and Operators should concentrate
  on keeping their segment of the production process running smoothly.
- ➤ The Technology Transfer Documentation Generally interpreted as document indicating contents of technology 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. It is duty of Quality assurance department to check and approve the documentation for all processes of technology transfer.
- The Development report The R&D report is a file of technical development and R&D department is in-charge of its documentation this report is an important file to indicate rationale for the quality design of drug substances and its specifications and test methods. The development report is not prerequisite for the application for approval it can be used at the pre approval an inspection as valid document for quality design of new drug the development report given below.
- The data of pharmaceutical development of new drug substances and drug products at stages from early development phase to final application of approval.
- The information of raw materials and components.
- The Design of manufacturing methods.
- The change in histories of important processes and control parameters.
- The Specification and test methods of drug substances.
- The validity of specifications range of important tests such as contents impurities and dissolution.
- The verifications of results.

- **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.
- The Report The completion of technology transfer is to be made once data are taken accordingly 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.
- ➤ The Exhibit After taking scale up batches of the product manufacturing of exhibit batches takes place. In case of exhibit batch sizes are increased along with equipments and their processes this is done for filling purpose in regulatory agencies.

## **Technology Transfer Procedure Standard Operating Procedure**

**Procedure for Manufacturing and Packaging:** After the completion of three validation and commercial batches R&D shall prepare the technology transfer dossier (TTD) which shall be reviewed by Head Production, Head QC, and Head Engineering and approved by Head QA. The dossier shall contain the details of unitary formula process flow chart raw material and packing material specification in process and finished product specification master formula card, safety parameters and critical steps, critical process parameters and their specification and measures response process validation protocol, process validation report, stability data, deviation and change control and product development reports. Then after successful transfer of technology manufacturing process, manufacturing of the respective product is the responsibility of production department if any problem arises QA shall investigate and refer to R&D through investigation report in the form of Inter Office Communication (IOC) and any deviation in the process shall be supported by deviation and change control form as applicable. For the third party and loan license products of the respective organisation will provide the TTD-QA and manufacturing process shall be demonstrated to production personnel on minimum of two and three batches.

- > Procedure for Analytical Method Transfer (For Drug Product): The Analytical method transfer shall be initiated by analytical department for all the validated methods the analytical department analyst along with quality control analyst has to perform analysis as per the analytical method transfer protocol the transfer activity shall be established on the optimization batch or process batch with the final formula and prepared by R&D, reviewed by DQA, QC and finally approved by QA the analytical method transfer protocol shall explain the transfer activities of the drug product and also the parameters that shall be transferred are assay, Dissolution related substances content uniformity and residual solvents in case of multiple strengths analytical method transfer shall be performed for lower strength. All chromatograms record of results and other information have to be interlinked and records have to be maintained a report has to made with summarized results and conclusions and the same shall be reviewed by Head DQA, Head QC and approved by Head QA it is considered to be completed upon the certification by analytical department, quality control and quality assurance that the method under consideration meets the acceptance criteria and finally analytical method transfer report shall be prepared.
- ➤ Procedure for Analytical method transfer (For Drug substances) Non Pharmacopoeial Methods: The vendor has to transfer the analytical methods to QC in case if the analytical method transfer activity was not performed by the vendor the same shall be prepared by AR&D as per the STP.
- ➤ Procedure for Analytical method transfer (For Drug substances) Pharmacopoeial Method: The vendor has to transfer the analytical method to QC if the methods are same as per respective pharmacopoeia the method suitability shall be performed by AR&D suitability of the analytical method shall verified by performing the specificity and precision study and same shall be reviewed by DQA and communicated to QC. The analytical method transfer protocol and report shall be prepared and its explain the transfer activities of the drug substance and also the parameters were transferred are assay residual solvent and related substances a limits and parameters described for drug product and drug substances are indicative but shall altered based on customer's requirements and nature of drug product and drug substances to be followed as per rules and protocols then documentations for analytical method transfer activity was be successful by analytical R&D department.

## The Technology Transfer Team

Sr. No.	Name of Team Member	Responsibilities of Team Member
1	Process Technology	The central focus for transfer activities.
		Collates documentation from donor site.
		Performs initial assessment of transferred project for feasibility,
		compatibility with site capabilities and establishes resource requirements.
2	QA Representative	The reviews documentation to determine compliance with marketing authorization.
		The reviews analytical method with QC to determine capability, equipment training requirements.
		The initiate's conversion of donor site documentation into local systems and format.
		Confirms regulatory requirements that are change to manufacturing license, variation to MA if process changes needed.
3	Production Representative	The reviews process instructions/ rules with process technologist to confirm capacity and capability.
		They consider any safety implication Ex. Solvents, toxic and sanitizing materials.
		They consider impact on local standard operating procedures.
		They consider training requirements of supervisors and operators.
4	Engineering Representative	The reviews with production representative equipment and requirements.
		Initiates required engineering modifications change or part purchase.
		Reviews preventative maintenance and calibration impact Ex. Use of
		more aggressive ingredients, more temperature sensitive process and modifies accordingly.
5	QC Representative	The reviews analytical requirements.
		The availability with instruments.
		The responsible for analytical method transfer for drug substances and drug product.

## **Technology Transfer Plan**

The technology transfer of test method it is required to clarify validation range and acceptance criteria of conformity of technology transfer regarding individual test methods to be transferred and the validation range Ex. Full validation, reproducibility it should be judged on the basis of results of evaluation of technologies facilities and equipments of transferred party and the range may be influenced by information to be contained in the technology transfer documentation. To compare test results including dose range number of batches specific test methods to be used in the transferring and transferred parties should be specified.

Technology information to be described in or attached to the technology transfer plan-Information of raw materials: Summary including physical and chemical properties and stability name and structural formula and stability data. The specification and test method specific test method and specifications, change history of specification and test methods and its rationale finally the results of analytical validation. List of reference standards test results should be attached information of toxicity and stability for laboratory use and a list of subject samples for comparative evaluation and their test results.

## **Effective Factors in Technology Transfer**

The technology transfer process entire elements of the technology triangle that is technical organisational and cultural aspects are to be transferred into organizations and not impose them solely into technology hardware parts they should be fully cognizant of their capabilities and requirements before launching technology transfer. The technology transfer evaluation, requirements and capacities recognition and selection of technology methods are of vital importance in the technology transfer process thus awareness of effective factors on technology transfer is of great importance for technology recipients.

## The Importance of Technology Transfer in Pharmaceutical Industry

- ➤ To elucidate necessary information to transfer technology from R&D to actual manufacturing by sorting out the different information obtained during research and development and the technology transfer of existing products between different manufacturing places.
- ➤ To specific procedure and points of concern for the two types of technology transfer in the above to contribute to technology transfer it is applies to the technology transfer through R&D and production of drug that is chemically synthesized drug substances and drug products and the technology transfer related to post marketing changes in manufacturing paces.

## What is technology transfer?

For the purpose of this Q and A technology transfer refers to the formal licensing of inventions, software, research tools, and other technologies developed within a university research programs and usually protected under United States intellectual property laws. In a broader sense technology transfer may also include the dissemination of knowledge and discoveries to students, other academics, industry, scientists, and general public in that respect technology transfer is another way for a university to teach and there by disseminate knowledge for public utilization. Traditional routs for such dissemination to occur that is classroom discussions, attendance and presentation at conferences, publication in the

scientific literature and the employment of students by companies. The technology transfer also can involve a number of different forms of intellectual property such as original works of authorship copyrighted by university faculty, trademarks, individual know how and tangible research materials this Q&A discusses university technology transfer occur when innovations are licensed by a university to an organization usually a for profit organisation that commits to further develop these early stage technologies into commercial products. The objective of this technology transfer is to create goods and services that will benefit and be generally available to the public.

## Why is Technology Transfer Important?

There is a clear need for pharmaceutical companies to speed up delivery of new drug products to the market to maintain competitive effectiveness new drug discoveries must be rapidly brought to market to generate cash flow to re-invest back into the business and support the drug pipeline it is estimated that 75% of new products on the market fail to recoup the costs of R&D. The number of new medicines launched in recent years has slowed down because it has become more difficult to meet all the requirements of safety, clinical and regulatory in areas of unmet medical need. Statistics from the pharmaceutical industry success rates show that there is a high risk of failure in drug discovery and development with only one in five to one in ten new candidate drugs nominated from research to development actually achieving registration and reaching the market. The rate at which pharmaceutical companies are clearing the final hurdle of clinical trials has declined since the mid-1990s when 57 new chemical entities (NCE) that is small synthetic molecules were approved in 1996 down to only 29 worldwide approvals of new molecular entities in 2002 on average an NCE takes 10 to 12 years of research and development from drug discovery to product launch. This drug development times have increased in recent years because all phases of development are taking longer the initial concept testing stage can be completed in less than two years if more work to assess the risk is conducted during drug discovery.

## What have been the accomplishments and results of the technology transfer activities of universities?

One measures of the accomplishment of university technology transfer programs is the number of new commercial products that are available to the general public as a result of university technology transfer in fy 2005 alone the association of university technology transfer manager (AUTM) reported that various different new commercial products were

introduced that were a result of a university technology transfer. Over the last decay nine years approximately 3723 new products have been introduced that are the direct result of university technology transfer in a broad array of fields including medicine, public safety, food and agriculture, new materials, education and communications. Example Erbitux – a chemotherapeutic for various types of cancer including colorectal cancer developed by scientists at the University of California, San Diego. Fast-Act – A Nano-material invented at Kansas State University and licensed to Nano-scale materials Inc. The Nano-particle material absorbs, immobilizes and detoxifies hazardous and toxic material spills.

How do technology transfer officers gain the experience and skills necessary to do their jobs effectively? The effective technology transfer requires a diverse set of skills scientific expertise, technical assessment, market evaluation, intellectual property law, marketing, negotiation skills, contract law and knowledge of appropriate federal laws are all essential in the technology transfer profession often these are skills that are developed over years of experience. The university seek new employees for their technology transfer office from fields where they have already developed some of these key skills and business development or technical marketing are two areas that can produce candidates with many of the skills that are desired. In addition to a diverse skill set technology transfer also requires that the individual carefully balance the academic mission of the institution with the business mission of the technology transfer office the cultures, goals and mission vary from one academic institution to another and from one company to another company experienced and effective technology transfer professional understand the differences between the academic culture and the business culture have the ability to communicate these differences in a meaningful way to all stakeholders in a negotiation and also have the experience to craft relationship that carefully balance the needs of the parties. At a times this is likely to require close collaboration with colleagues in other unit of the university that either support research such as sponsored programs a regularly interact with companies such as development.

## **Publicly Developed Technology**

There are two quite different sources of funding for new technologies the public sector including universities and the private sector each funds research in its own sector as well as research in the other sector the balance varies heavily from industry to industry, nation to nation and time to time. In pharmaceutical example the balance is shaped by the budget of public sector establishment such as the United States National Institutes of Health (NH) and

by the magnitude of research and clinical testing by the pharmaceutical industry. The early development of computers was subsidized heavily by the government while contemporary research and engineering of computers that is other than for military applications is supported primarily by the private sector. The balance between public and private sector expenditures is more weighted in favour of the public sector the numbers almost certainly show that developing world public sector research far outweighs developing world private sector research but it is probably also the case that the developing world public sector supplies far less technology to the developing world economy than does the international private sector. The role of public sector support is generally more one of building a capable infrastructure than of creating new developing world industries.

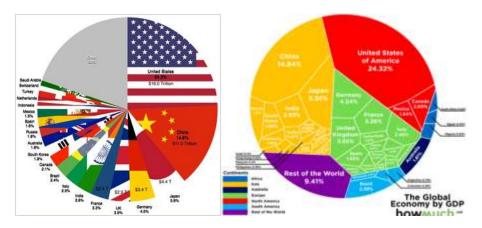


Figure of the Technology Transfer of Global World Economy.

## **Private Sector Developed Technology**

The privately developed technology as noted previously outside a few specific sectors such as parts of agriculture the primary means of technology transfer to developing nations is probably through commercial transfer from the developed world private sector through licensing or FDI participation in this private sector network is the normal way for a developing nation firm to gain its first technology. Depending on the sector and the nation the firm may go on to gain a substantial role in the international production chain sometimes with its own technology and may ultimately produce its own product for the domestic market for export.

## **Function of Technology Transfer Team**

The coordinating between technology users and developer between researcher and manufacturers is important element of technology transfer a main ingredient for moving technology from a research laboratory to new business enterprises successfully in an

environment that is supportive for entrepreneurship link cataloguing resources related to business enterprises and connecting would be entrepreneurship researcher and other technology developers to outside group and organization which can help in the process of starting new product companies such linkage provide referrals for individuals business counselling sources of financing.

## Findings on Initiatives for local production and Technology Transfer

The development of local pharmaceutical production capacity is a complex endeavour involving many types of activity the institutes identified by this study undertook a broad range of activities and varied widely along a number of dimensions given below;

- ➤ The level of development of partners north south and south-south type of technology transfers-transferees, private to private actors, public to private, private to public scale of projects from individual consultants to small nongovernmental organisation (NGO) to small, medium sized enterprise to large multinational enterprises.
- ➤ The goals and interests of transferors and transferees complexity of transferred technology and technical capacities of transferees from packaging to API production the technical value of the transfer from replicating existing knowledge no gain for transferees to providing valuable new technology.
- ➤ The economic value of transfer from virtually nonexistent product market to substantial market size scale and duration of transfer from four weak to ten weak.

## When technology transfer is done

- The idea to discovery lab.
- > The discovery lab to development lab.
- > The development lab to pilot plant.
- ➤ The Kilo lab to pilot plant.
- The pilot plant to semi works, i.e. other pilot plant.
- > The pilot plant to manufacturing.
- > The manufacturing to manufacturing.

## The Success of Technology Transfer

- ➤ The Communication: Open communication between all team members.
- > The Direct communication between technical members.
- ➤ The effective and timely communication with regulators.
- The Sending and Receiving Unit: The technology transfer is not a one way street.

- > The sending unit and receiving unit must be equally involved in the process to ensure success.
- The Team work at all time.

## **CONCLUSION**

In pharmaceutical industry the technology transfer involves cost and expenditure that is negotiated and agreed upon by the transferee and transferor the transfer may be said to be successful if the transferee can successfully utilise the technology for business gains and eventually assimilate it use of enriched approaches like technology transfer to the development and start-up of new production systems will enable pharmaceutical organisations to fully benefit from the recent improvements in the new drug discovery and to complete more effectively in a rapidly changing marketplace. The pharmaceutical industry technology transfer means action to transfer of information and technologies necessary to realize quality of design of drugs during manufacturing. The plan must be communicated to the involved parties in research at the corporate level and at the production site and is effective technology transfer is critical to success in pharmaceutical industry. A healthy communication between different countries and different organizations are the key to the success of technology transfer and development in pharmaceutical industry is important to upgrade the quality of design to the quality of product and to ensure stable and high quality of product it is desire to make sure that is what, when, and why information should be transferred to where and by whom and how to transfer then share knowledge and information of the technology transfer each other between drugs manufacturing. A plan must be devised to organize the personnel and the process steps and once prepared it must be communicated to the involved parties in research technology transfer is an integral part of increasing innovation in an economy to achieve economy development and capitalize on public investment in research and development.

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