Pharmaceutical Technology Transfer Process: A brief Review

Abstract:
Technology transfer is a thought process to get the product scale from a developing site to commercial producing manufacturing facility. As manufacturing commercializes the products, some business strategy changes to get benefitted, every change after and before the approval needed the technology transfer. It involves the various process from sending unit to receiving unit, developing site to commercial unit. Technology transfers are performed for various reasons. Technology transfer is not related to provide only documented thing to complete the transfer of technology, it involves the monitoring of executions, trial for the manufacturing feasibility at site, troubleshooting during the submission batches. After the completion of execution of batches to filing of that product to regulatory agencies and replying to their queries related to the process developments. It comes up to the launch of that product to the commercial market, technology transfer needed.

Introduction:
The term "Technology Transfer" in Pharmaceutical sector refers to the process of progress from drug discovery to development, clinical trials and ultimately full-scale commercialization. It's an essential step that forms a bridge between drug discovery and also the development of a brand new medicative product.
As per WHO, "a logical procedure that controls the transfer of any method in conjunction with its documentation and skilled experience between development and manufacture or between manufacture sites.It may be outlined because the flow of technology from transferor or developer to the transferee to induce an advert profit when undergoing commercialization. It conjointly involves the application of transferring scientific findings from one organization to a different for additional development of existing merchandise or transfer of technology between the two production units.

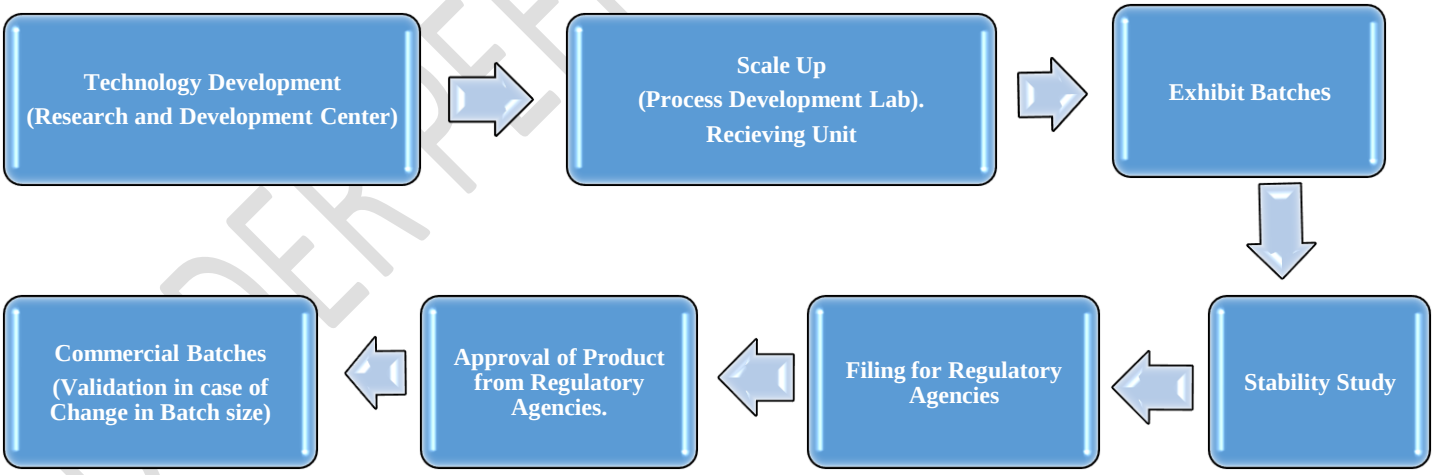

Table Number 01. Flow Chart of Technology Transfer

Process of Technology Transfer

A. **Technology Development** – The Research and Development i.e. Sending Unit develop the Technology. The formulation development team works on the development of formula for the proposed dosage form by doing the literature review, preformulation study, formulation development by taking trial at lab scale equipments, verifying the critical attributes by analysis and development at Analytical development lab. Upon building confidence of developed formulation, start transferring the technology to the receiving unit.

B. **Scale Up at Receiving Site**–At Receiving site scale up trials are performed for multiple reason such as equipment feasibility, process problems or defining CQA's etc. there are multiple aims to perform the trials. After confirming the all critical process parameters and CQA are within the defined criteria. Pilot bio batch will be taken, to confirm or to take the decision that need to go for Exhibit or submission batches or need to rework on the development. After successful pilot scale bioavailability study, we can go for Exhibit batches.During the transfer from analysis and development to produce the right documentation of the detail of the merchandise and method is two-handed over to the assembly department by the analysis and development department within the type of written record. It includes:

I). Technology Transfer Dossier (TTD): Technology Transfer is written record (TTD) analysisand development provide technology transferwritten record (TTD) document to developmentlaboratory that contains all info of formulationand drug product.

II).Master Formula Card (MFC): Shaping the producing directions, status needed, generic name, strength, master formulation record number. masterpackaging record number. SPS, STP numbers.

III). Master Formulation Record (MFR): It providesan elaborated description of status needed forproducing at the site and the steps concerned inproduction.

IV). Master Packaging Record (MPR): It providesinfo relating to the kind of packaging material tobe used, the steadiness and also the shelf life ofpackaging material.

V).Specifications (SPS): These area units the standard side establishing the link between higher andlower producing limit.

VI). Standard Test Procedures (STP): These areaunits the quality procedures either taken fromany of the aggregation or were set in-house.

C. **Exhibit or Submission batches**- Exhibit batch is created during a production plant or maybe during a pilot plant but it should have similar equipment like that in the production plant. The batch size should be in and of itself so the steadiness study is conducted in each accelerated and long-term conditions. the most aim of exhibit batch is to get stability information as per the ICH guideline to submit for an ANDA (Abbreviated New Drug Application) application and to induce the restrictive regulatory approval.

D. **Stability Study** - Stability studies of the drug or drug substance is conducted of three consecutive batches. within which an ample quantity of drug or drug substances is being collected and square measure unbroken for accelerated and long-term stability studies, that were then tested at pre-defined time intervals. A report generated by such studies is needed for filing to restrictive agencies.

E. **Filing and Approval of Product from Regulatory Agencies** – The Collected data from the Exhibit batches i.e. Batch records of execution of exhibit batches, process performance qualification protocol and report, Product development report, intended batch records, stability study reports, bioequivalence studies and the details of impurity analysis regarding the Drug product and Drug substances and other related documents or data asked by agency time to time in the review period.

F. **Commercial Launch Batches(Validation in case of Change in Batch size)-** Upon receiving approval form the regulatory agency, firm can launch the commercial or production batches to the market. In this scenario when the commercial launch batches are of same size as submission or exhibit batches taken then firm can go for direct commercialization. And in case of change in batch sizes as per market requirements (in most of the increase in batch size) scale up activity need to performed. When the launching firm go for scale up launch, SUPAC (Scale Up And Post Approval Changes) guidelines to be followed. Batch size can be increase up to the 10 fold of exhibit

batch. At the same time Commercial validation need to be performed and change in batch needs change in capacity of equipments, run time of machines and other related scale dependent factors. The aim behind running three consecutive batches square measure to shows method consistency, dependableness and to demonstrate that the producing method is in restraint throughout all the stage,As Critical Process Parameters needs to validated and to confirm the change in batch size does not affect the predefined Critical Quality Attributes.

Site Transfer of Product

There many circumstances, when Firm or private industry needs to keep the alternate manufacturing site ready to manufacture their existing commercial product. The main reason when regulatory agency put some restrictions to the firm or private industry as good manufacturing practices compliance issues. Some time to reduce the manufacturing cost, firm can transfer their existing commercial product to another manufacturing site. If the demand rises, the producing facilitiesweren't ample to fulfil the need at that point additional collaboration between the developer and another producing unit to induce reciprocally benefitted.

In the site transfer cases, a proper Evaluation and Gap assessments of Sending unit and receiving unit need to be performed. As sending unit and receiving unit may do not have same Equipment, equipment capacity, or same Standard Operating Procedure, or excipient vendors, etc. For the mentioned changes a detailed gap assessment finding need to be performed and way forward to be identified within regulatory compliances. The identified changes need to be informed to the regulatory agency in the form of Variations or annual reports.

Why Technology Transfer

There are several reasons why the technology developerconsiders making its technology be on the market for an additional person. To diminish the gap between and to make abridge between the educational institute and establishmentwith the business mission or to transfer technology fromone company to a different a skill full technology transfer isneeded. Company toughened and effective technology transfer skilled perceive the variations between the educationalculture which can involve correct communication and negotiation between the two parties

Technology transfer may occur from analysis labs tothe producing companies, which might be the drugdiscovered within the educational institutes or the drugdiscovered within the analysis and development units.In such quite technology transfer a mutual collaboration will result in generating the required fund for theanalysis labs and may additionally lead the producingcompanies to induce monetarily benefitted.

Scale Up and Post Approval Changes or Variations

All the changes performed in product after regulatory approval must be notified the approving agency as per the SUPAC guidelines. The changes are broadly classified as Major Moderate and Minor. Some of the changes are enlisted below with description.

Category of Changes as per US-FDA and EU-EMA

Changes or Variations	Admin	Minor	Moderate	Major
EU-EMA	Type IA	Type IA_{IN}	Type IB	Type II
US-FDA	Annual Report	CBE-O	CBE-30	PAS

CBE-O – Change Being Effected in Zero days; CBE-30 - Change Being Effected in Thirty days; PAS- Prior Approval supplementary changes

Table Number 02. Post A

The changes are broadly classified as Major Moderate and Minor. Some of the changes are enlisted below with description.

1. **Change in Batch Size:** When the approved product need to commercialized in the market, Business development unit of the industry analyses the market requirement of the product, and proposes the changes in the batch size of the product. It involves the scale up and scale down of the existing batch sizes. The proposed batch size requirements differ from the existing requisites. So the evaluation for proposal against the existing requisites need to be evaluated.
2. **Change in Active Pharmaceutical ingredient (API) Vendor:** When the business exigency occurs to make the product cost effective to induce the profiting or some time existing vendor unable to provide the required volume of API. So Manufacturing unit need to go for alternate vendor for API. Change is need to be evaluated in regulatory perspective as it comes under the major change. Similarly, process for change in vendor for other excipient (Except API) can be evaluated.
3. **Change in manufacturing Equipment/ area:** When the batch size changes proportionally capacity of equipment changes or some times to improve to process efficiency manufacturing equipments need to changed. Changes is depending on the how proposed equipment having specification that matches with the existing or having different principle.
4. **Change in manufacturing site:** As cost effectiveness or to induce the larger volume of product alternate manufacturing site needs to be ready. In case of regulatory compliances product need to be transferred for alternate site to ensure the effective market supply.
5. **Change Formulation concentration:** Allowed percentage of change in concentration can be made after approval of the products. And same to be notified to regulatory agency.

Factors Affecting the Process ofTechnology Transfer:

• **Cost-effectiveness:** The Technology transfer are performed considering cost effectiveness factor, the transferred technology must remain beneficial for the manufactures while commercializing the proposed product.
• **RegulatoryCompliance:** Pharmaceutical industry is the heavily supervised by the regulatory bodies, as in the medicines assurance of quality, safety and efficacy is the basic requirement and GMP environment should be followed.
• **Ethical practices:** It includes the fair practices should be followed by involved individuals and pharmaceutical industryto achieve success, it also covers the GLP, GDP practices must be followed by the manufacturing without any compromise.
• **Skilled Professional:** Every time there is introduction of new product at site, the trained and highly skilled manpower's are required to successful the aimed project. As the transferring technology required knowledge of proposed site or manufacturing unit and history of product development with analytical and process behavior of the product. The employees must be skilled so that they can also contribute to high productivity.
• **ProjectsTimeframe:** Every pharmaceutical industry aims to induce the profiting by performing the technology transfer so the proposed project also needs to complete within the stipulated time frame to gain the market volume, which converts the industry momentum for profiting.

Member of technology transfer Team

Whenever a replacement technology or formulation is formed and also the management decides to transfer it from the laboratory to the producing unit the team of delicate personnel's is being trained so they should become acquainted of the method and must work with the constant goal because the management goes with to realize the simplest doable action and the success of technology transfer depends upon the workforce concerned within the method from the invention at analysis level to its transfer to producing unit followed by its availableness to the market. The various persons involved in the process of technology transfer are:

•**Product Developer:** These are the person concerned within the development of product, method of analysis and development moreover as getting ready the general information associated with the formulation within the kind of a written account known as dossier.

•**QA Personnel's**: These are the key persons in the whole process of technology transfer their main function is to make a bridge between the research technologist and the manufacturing unit. Their work includes reviewing the documents received by the research lab, to understand it and to opt for the best possible process to implement it with no productivity loss. It is also the responsibility of the QA personnel's to be prepared for the regulatory requirement which may include preparing validation protocols, designing new SOPs if required, preparing master document such as manufacturing records personnel: Engineering department, change control, market complaint.

•**Production Personnel:** First of all, they cross verify the instruction provides to them by the QA Personnel's to confirm the capacity and capability of the manufacturing unit. It may include verifying the SOP's Master manufacturing records. Providing training to the operators and other manufacturing personnel

•**Engineering Personnel:** Engineering is responsible for controlling the temperature and pressure of a particular area. Along with the production team, it is also responsible to check and verify the calibration status of machines and equipment.

•**Quality Control personnel**: Quality Control department deals with setting up the testing procedures and testing specifications as well as the conducting the validating the analytical methods along with QA personnel, also are responsible to update the equipment status to QA and to perform the quality testing of the formulation prior and post-manufacturing.

•**QA personnel**: Perform final review including equipment qualification, testing procedures, maintaining the area formanufacturing, conducting validation and stability studies and finally releasing the particular formulation for commercialization.

As this is the teamwork training to each person in their respective field must be provided by QA with the help of management before starting manufacturing of the transferred technology to the manufacturing unit. So that productive result must be achieved

Conclusion

The pharmaceutical technology transfers process bridges drug discovery and full-scale commercialization. It transitions a product through R&D, scale-up trials, exhibit batches, stability testing, and regulatory filing. Key technical records like the Technology Transfer Dossier (TTD) and Master Formulation Record (MFR) ensure exact execution. Process parameters are strictly monitored to secure regulatory approval from agencies like the FDA or EMA. Post-approval modifications follow strict SUPAC guidelines, governing up to ten-fold batch size increases. Operational drivers include cost-effectiveness, capacity matching, and regulatory compliance shifts. Execution relies on interdisciplinary teams across R&D, QA, production, engineering, and QC. QA personnel act as a primary bridge to prevent any loss in manufacturing productivity. Comprehensive gap assessments manage variations in equipment specifications between sending and receiving units. Ultimately, this structured lifecycle guarantees process consistency, reliability, and sustained product quality.

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