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An Overview on Technology Transfer

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Abstract: For the development of Nation's Economy, it is essential to develop and work on various new ways of Technology transfer. It is a need of today to include innovative ideas to find out New horizons of Technology transfer. Innovation is a continuous process and attention should be given to make the Technology transfer more fruitful, cost saving and time saving.

A dedicated technology transfer organization should be set up to facilitate and execute the process. Nation should be built up with new technologies and its implementation. It is important to remove the barriers for free flow of science and technology.

Key words: Technology Transfer.

Introduction

In the pharmaceutical industry, technology transfer may broadly refer to the processes required for successful progression from drug discovery to product development, clinical trial and full scale commercialization, for the development and transfer of knowledge and manufacturing technologies of finished solid dosages forms. It is usually defined as transferring the product out of the development laboratories or the process development pilot plant into full commercial scale manufacturing facilities.

In cases where a secondary commercialization is necessary, it also involves transfer to different facilities in multiple regions and countries. Appropriate technology transfer includes the transfer of scientific information, capability, technological basis of the product and process, and analytical test methods from a knowledge center (donor) to the manufacturing plant (receptor). This process is important to ensure that product quality and performance build in during R & D remains unchanged in full scale commercialization product production. The establishment of technology transfer, process is complex process that typically involves multiple functional areas, such as pharmaceutical and analytical R & D, operations quality, regulatory affairs, and program management[1].

For a typical research-based pharmaceutical company, drug discovery and development can be broken down into distinct stages which are clearly described in Figure 1.

Technology transfer process in pharmaceutical industry:

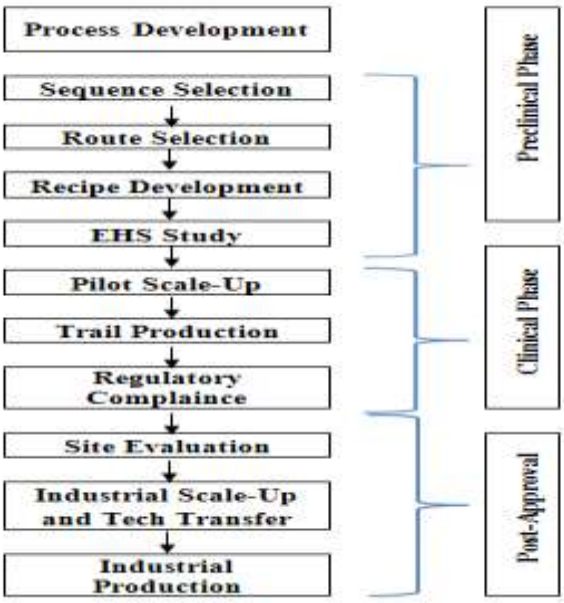

Figure 1: Typical process development work flow in pharmaceutical industry[2]

It is the process by which an original innovator of technology makes its technology available to commercial partner that will exploit the technology. So, there are 3 standards in the definition of technology:

- First, knowledge must be systematic. This means that it must be organized in terms of providing solutions to problems.
- Second, knowledge must exist in certain places like in someone's head or in documents, and must be able to be presented, so no matter what it means it must be able to be transferred from one person to another.
- Third, it must have purpose-orientation, so that it can be utilized for useful purposes in industry, farming, and commercial fields[3].

Technology transfer is the process by which developers of technologies make its technology available to a commercial partner, that will exploit the technology. There are two types of Technology Transfer, Vertical and Horizontal. Vertical Technology transfer refers to transfer of technology from basic research to development and production respectively, whereas Horizontal Technology transfer refers to the movement and application of technology used in one place or context to another place.

According to WHO, Transfer of technology is defined as "a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites". It is a systematic procedure that is followed in order to pass the documented knowledge and experience gained during development and or commercialization to an appropriate, responsible and authorized party. Technology transfer embodies both the transfer of documentation and the demonstrated ability of the receiving unit (RU) to effectively perform the critical elements of the transferred technology, to the satisfaction of all parties and any applicable regulatory bodies[4,5].

The development and transfer of knowledge and technology has been and will continue to be critical to success in pharmaceutical industry. The transfer of technology is considered as both fundamental and significant to the drug discovery and development process for any new medicinal entity. This process is important for to elucidate necessary information for technology transfer from R & D (Research &Development) to PDL (product development laboratory)[4].

Technology Transfer in Pharmaceutical Industry has been viewed from the perspective of Innovation and Research & Development. Since research is carried out in laboratories on small scale before it could be produced on commercial scale. Thus, Technology Transfer is important for such research to materialize on a larger scale for commercialization especially in case of developing and under developing countries. Technology Transfer is an integral part of New Drug Discovery and development of new medicinal products. Thus if Technology Transfer process to production site is carried out at an affordable cost, the cost of product development would not raise during pilot scale up.

For successful technology transfer of a product, the Departments responsible in a pharmaceutical industry are:-

- Research & Development,
- Production,
- Engineering,
- Quality Control and
- Quality Assurance[7].

The various departments responsible for technology transfer process are described in Figure 2.

Flow Chart Of Typical Technology Process[2,4]:

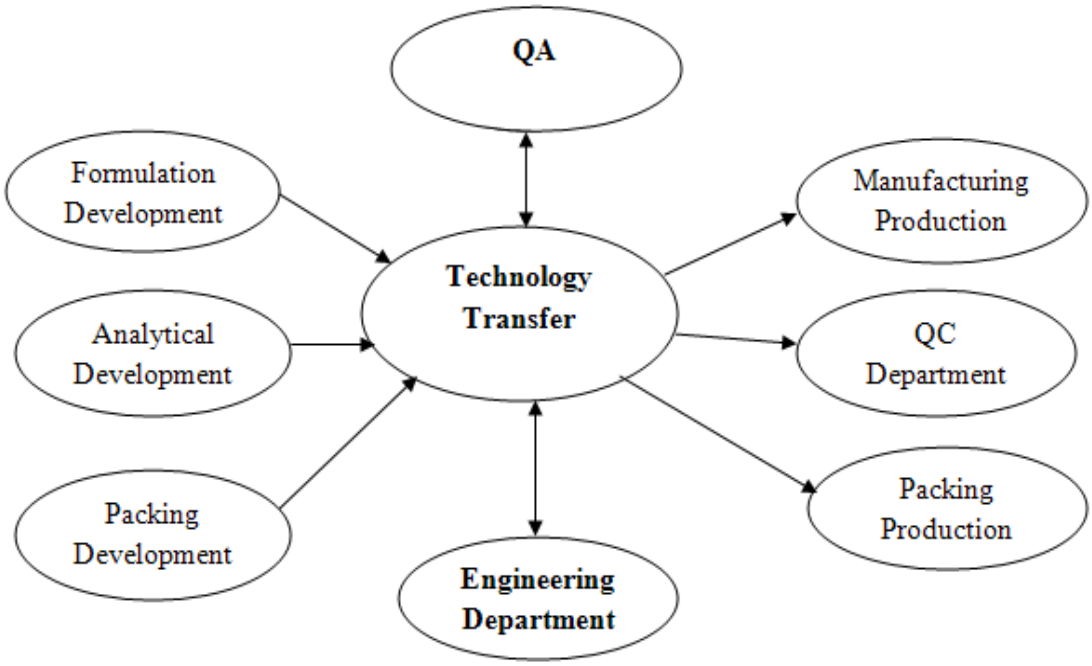

Figure 2: Typical Technology Transfer Flow Chart

Technology Transfer is the intersection between business, science, engineering, law and government. Technology transfer is the process by which basic science research and fundamental discoveries are developed into practical and commercially relevant applications and products. Whether a tablet, a transdermal patch, a topical ointment, or an injectable, the transformation of a pharmaceutical prototype into a successful product requires the cooperation of many individuals[8,9].

Traditionally, technology transfer teams were charged with moving a physical process from research and development into production while that the role remains critical, today's transfer team plays a larger part, helping the company attain its strategic goals throughout the product life cycle[10].

The research is also intended to propose some regulations to realize technology transfer necessary for high quality and stable manufacturing of developed products and existing products by reviewing technology transfer based on the following ideas.

- The technology transfer means actions to transfer information and technologies necessary to realize quality of design of drugs during manufacturing.
- Appropriate technology transfer is important to upgrade the quality of design to be the quality of product, and ensure stable and high quality of the product.
- It should be noted that drugs may influence human lives and health, and their raw materials, compositions and manufacturing methods are changed during their long term manufacturing and marketing.
- To assure the drug quality, it is desired to make sure 5 W's and 1 H, 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 drug product between transferring and transferred parties.
- The technology transfer does not mean one time actions taken by the transferring party toward the transferred party, but means continuous information exchange between the both parties to maintain the product manufacturing[11].

The successful technology transfer from research and development (R&D), the transferring site, to the commercial Production site, the receiving site, is a critical process in the development and launch of a new medicinal product. It can be extremely costly for a company if things go wrong during the transfer process, resulting in delays to launching a new product on the market and lost sales. Also, it can take increased resource, time and cost to make corrective actions following an unsuccessful transfer. Progressive pharmaceutical companies are therefore placing more attention to streamlining and optimizing their technology transfer process to ensure the rapid and successful introduction of a new medicinal product to market[12].

WHO Guiding Principles Of Technology Transfer[13]:

WHO guiding principles on transfer of technology are intended to serve as a framework which can be applied in a flexible manner rather than a strict rigid guidance. Focus has been placed on the quality aspects, in line with WHO's mandate.

1. Transfer of processes to an alternative site occurs at some stage in the life-cycle of most products, from development, scale-up, manufacturing, production and launch, to the post-approval phase.
2. Transfer of technology is defined as "a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites".
3. The ever-changing business strategies of pharmaceutical companies increasingly involve intra- and inter-company transfers of technology for reasons such as the need for additional capacity, relocation of operations or consolidations and mergers. The WHO Expert Committee on Specifications for Pharmaceutical Preparations, therefore, recommended in its forty-second report that WHO address this issue through preparation of WHO guidelines in this area.
4. Transfer of technology requires a documented planned approach using trained and knowledgeable personnel working within a quality system, with documentation of data covering all aspects of development, production and quality control. Usually there is a sending unit, a receiving unit and the unit managing the process which may or may not be a separate entity. For "contract manufacturing" please see good manufacturing practices (GMP).
5. In order for the transfer to be successful, the following general principles and requirements should be met:
    - The project plan should encompass the quality aspects of the project and be based upon the principles of quality risk management.
    - The capabilities of the sending unit (SU) and at the receiving unit (RU) should be similar, but not necessarily identical, and facilities and equipment should operate according to similar operating principles;
    - A comprehensive technical gap analysis between the SU and RU including technical risk assessment and potential regulatory gaps, as needed.
    - Adequate trained staff should be available or should be trained at the Receiving unit;
    - Regulatory requirements in the countries of the SU and the RU, and in any countries where the product is intended to be supplied, should be taken into account and interpreted consistently throughout any transfer programmed project.

- There should be effective process and product knowledge transfer.
- Technology transfer can be considered successful if there is documented evidence that the RU can routinely reproduce the transferred product, process or method against a predefined set of specifications as agreed with the Sending unit.
- In the event that the RU identifies particular problems with the process during the transfer, the RU should communicate those back to the SU to ensure continuing knowledge management.
- Technology transfer projects, particularly those between different companies, have legal and economic implications. If such issues, which may include intellectual property rights, royalties, pricing, conflict of interest and confidentiality, are expected to impact on open communication of technical matters in any way, they should be addressed before and during planning and execution of the transfer.
- Any lack of transparency may lead to ineffective transfer of technology.
- Some of the principles outlined in this document may also be applicable to manufacturing investigational pharmaceutical products for clinical trials as part of research and development, but this is not the main focus of this guidance and has been excluded due to the complexity of the processes.

Definitions:

According to Hashim Ahmad Technology transfer is defined as "The process of transferring information on bulk drug substance, formulation, manufacturing, packaging, testing, quality and safety between work units of development and manufacturing organizations with the goal of producing a marketable dosage form."[14]

As per WHO guidelines of Dr. S.Kopp Transfer of technology is defined as "a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites."[13]

Amrita K. defined process of Technology transfer (TT) as "the transfer of the manufacturing process for a new pharmaceutical Drug Substance (DS) and Drug Product (DP), respectively, from the transferring site (in this case R&D) to the receiving site or designated commercial manufacturing site." This includes all the associated knowledge, information and skills to be able to manufacture the DS and DP at the receiving site[5].

"Transformation of Active Ingredient In To a Dosage Form"[14]

Manufacturing process

Drug Substance + Excipients ----------> Drug Products

Analytical Process

Solid dosages form transfer locations[14]:

Transfer

New Product: R & D---------->Plant Demo trials--->Production (Validation)

Transfer

Existing: Plant A----------> Plant B---------->Production (Validation)

Demo Trials

Scope of Technology Transfer[8,15]:

Each time there is a change in scale, there is technology transfer. Technology transfer is critical for achieving rapid scale-up with control over how the manufacturing process is achieved. A general recipe can be converted into a master recipe for batch control in a specific plant at a given scale. "This conversion is a matter of identifying which recipe parameters are sensitive to scale and replacing class-based parameters with instance-based parameters."

Ideally, development and manufacturing teams share a common information model for process definitions. "This model would capture process definitions and parameters in a machine-readable format that can be rendered into documents for human interactions.

The technology transfer business formed in accordance with the demand increases in this kind of technology outsourcing can make it simple and efficient along with market activation. If the required technology can be supplied easily and competitively, this can reduce the need and scale of in-house R&D, and will be useful for companies in securing competitiveness through the preoccupation of opportunities in the market. Furthermore, in terms of costs, there is a strong point in that cost savings can be gained with the reduction in R&D organization maintenance costs.

Start up and process definitions directly affect manufacturing yield and waste. When technology transfer transmits Quality by design (QbD) limits and definitions to manufacturing, "waste is reduced by eliminating trial and error in setting up the process," By giving manufacturers complete knowledge of the process and a framework for continuous improvement, technology transfer improves yields.6 In several ways; technology transfer enables continuous improvement of the manufacturing process. After ensuring that the process is clearly defined with general recipes, technology transfer sets the stage for recipe harmonization. Recipe harmonization, the use of common formats for all recipes across the product life cycle, forms a basis for process-knowledge management.

When technology transfer is performed correctly, it benefits all stages of a product's life cycle. To begin with, "technology transfer, combined with QbD and programmatic interfaces to commercial manufacturing systems, greatly reduces time to market.[6] Effective technology transfer affects time to market most during the 12–48-month period it takes to scale up from pilot to commercial scale. Recipe harmonization and normalization can reduce the time to achieve commercial-scale production by months.

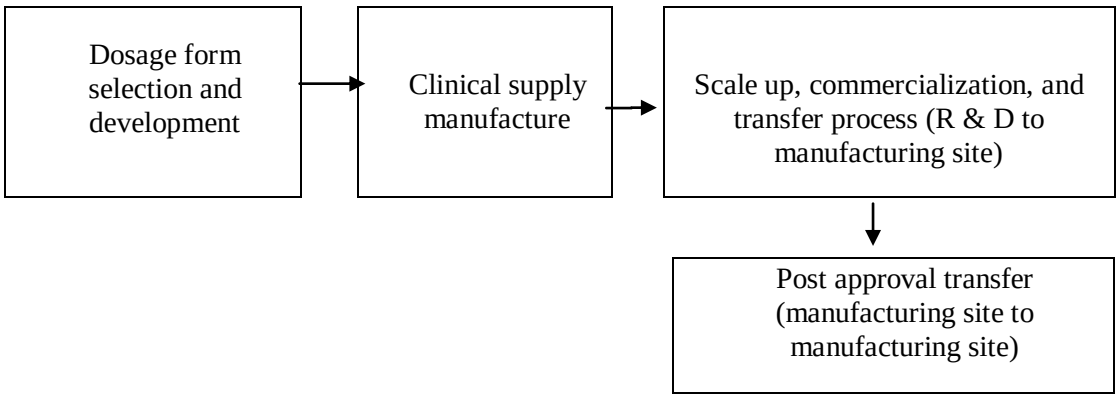

Figure 3: Scope of Technology Transfer

Technology transfer from R & D to manufacturing site[16,17]:

a. The transfer of technology from R & D (sending unit) to manufacturing site(Receiving unit) is the key step to getting a high quality to the marketplace.
b. A thorough review, manufacturing modes of operation (including batch size and recommended equipment) can be proposed for the initial scale up batches.
c. R & D should recommend any in process tests and tentative finished product specification, which have optimized for the formula.
d. During initial scale up batches, all processing parameters and finished product specification should be challenged.
e. Once a final manufacturing has been established, key process data and product specification should be tracked closely to establish normal process variability.

Technology transfer from manufacturing site to manufacturing site[16,17]:

a. Before a currently approved commercial product is transferred from one manufacturing site to another, documentation information about the process and testing should be gathered, evaluated and transferred.
b. Approval manufacturing, packing, cleaning, testing, and storage procedure should be conducted at the receiving unit.
c. A review of existing process validation reports and annual product review should be conducted prior to the start of any validation efforts.
d. A justification for all processing ranges and all in-process specification should be confirmed.
e. Operation and quality departments at both sending and the receiving units have responsibilities in transferring the manufacturing, packing, storage, and testing of products for one site to another, and assuring that the product produced at the new site is to comparable quality to product produced at previous site.
f. An additional responsibility is to ensure that all filling and regulatory requirement are meet.

Importance Of Technology Transfer[8,10,15]:

- ✓ The more effectively knowledge is shared within an organization, the more efficiently the organization can operate.
- ✓ Continuous improvement is possible through incremental knowledge.
- ✓ New information may then become explicit knowledge i.e. knowledge that can be set down in procedures, handbooks or process maps.
- ✓ Knowledge transfer within a company can called as "organizational learning". Traditional means such as handbooks, policies, SOP's and even E-mail can facilitates organizational learning, but additional means must be considered in order to share knowledge more effectively.
- ✓ Technology transfer team represents all stake holders, from development to engineering to production.
- ✓ Technology transfer team includes professionals representing supply chain management, packaging and health and safety.
- ✓ It encourages use of technology developed using taxpayer rupees to benefit society.
- ✓ It demonstrates research program relevancy and value.
- ✓ It permits researchers to partner with the private sector, leverage resources, and share ideas in a protected environment.
- ✓ It gives increased visibility to researchers and enables them to generate and earn royalty income.
- ✓ Innovative R&D.
- ✓ Drug Approvals.
- ✓ Compliant and effective commercialization.
- ✓ Ensure safe, pure and effective drug product.
- ✓ Consistent interpretation of GMP regulations.
- ✓ Bring new, more effective products to market faster.
- ✓ Cost effective production and distribution.
- ✓ Superior return on investment to shareholders / stakeholders.

When Does Technology Transfer Occur?[8]:

- ➢ Idea to Discovery Lab.
- ➢ Discovery Lab to Development Lab.
- ➢ Development Lab to Kilo Lab.
- ➢ Lab to Pilot Plant.
- ➢ Kilo Lab to Pilot Plant.
- ➢ Pilot Plant to Semi-works (other pilot plant).
- ➢ Pilot Plant / Semi-works to Manufacturing.
- ➢ Manufacturing to Manufacturing.

Facets Of Technology Transfer[7,18]:

The Transfer of Technology could happen in any of the following ways,

a. Government lab to private sector.
b. Between private sector firms to the same country.
c. Between private sector firms to other countries.
d. From academia to private firms.
e. Academia, Government and industry.

Regulatory Factors[19]:

From a regulatory standpoint, the main factors for a successful technology transfer are,

1. The presence of an acceptance criteria or specification for the product, process, or method, been established.
2. The established of adequate facilities, equipment/instrumentation, and trained personnel to accept a transferred technology.
3. The establishment of protocols and SOP's which executes technology transfer.
4. Data: there is documented evidence that the receiving unit, compliance with the agreed acceptance criteria, can successfully reproduce the product, process or method.

Business Factor[19]:

From a business perspective the success of a technology transfer is based on a balance between

1. Cost
2. Capacity/volume
3. Equipment and facility capabilities
4. Time frames
5. Regulatory requirements.

Requirements For Technology Transfer[14]:

- **Bulk Drug:**
  - Synthesis.
  - Supplier for raw materials / intermediate.
  - Cleaning validation.
  - Stability / storage.
  - Safety / Handling.
- **Analytics:**
  - Specifications of bulk drug and drug product.
  - Validated analytical method.
- **Drug Product:**
  - Formulation.
  - Raw material supplier.
  - Safety / handling.
  - Manufacturing procedure.
  - Manufacturing equipment.
  - Cleaning assessment.
  - Packaging.
  - Stability / storage.
  - In-process controls.

Key Factors To Ensure Success In Technology Transfer[14,16]:

- R & D and pilot equipment similar to production.
- Gain more experiences on large scale clinical lots.

- Validate process and analytical methods during development in R & D.
- Good communication and documentation.
- The natural progression in a product development life cycle, from a discovery laboratory, through scale-up and clinical development, to commercialization.
- Need for additional capacity.
- The strategic requirements to relocate business units because of economic advantage in different regions of the world.
- The by-product of corporate mergers and consolidations.

The transfer protocol should list the intended sequential stages of the transfer.

The protocol should include[13]:

- Objective.
- Scope.
- Key personnel and their responsibilities.
- A parallel comparison of materials, methods and equipment.
- The transfer stages with documented evidence that each critical stage has been satisfactorily accomplished before the next commences.
- Identification of critical control points.
- Experimental design and acceptance criteria for analytical methods.
- Information on trial production batches, qualification batches and process validation.
- Change control for any process deviations encountered.
- Assessment of end-product.
- Arrangements for keeping retention samples of active ingredients, intermediates and finished products; and information on reference substances where applicable.
- Conclusion, including signed-off approval by project manager.

Reason for technology transfer[6,7,20,21]:

- For the shearing of knowledge within organization.
- To enhance the manufacturing capacity.
- To launch product commercially.
- For the enhancement of marketing and distribution capability.
- Exploitation in a different field of application.
- To reduce the project cost.
- Due to that ideas are shared in a protected environment.
- It gives increased visibility to researcher.
- Lack of marketing and distribution capability.
- Form technology alliance to exploit each other's strength.
- When developer has no commercial capability.
- Application in different field.

Barriers Of Technology Transfer[3,7,21]:

- Lack of efficiency: Automation of production process to improve efficiency and lower cost.
- Lack of market share: Local producers face significant challenges in meeting international Quality standards and capturing a critical market share. Greater market share would increase profitability.
- Cost of prequalification: There is benefit in meeting international standards since it opens up the opportunity for trading across the entire world.
- Labour issues: The pharmaceutical sector demands relatively skilled labour. High labour turnover and absenteeism owing to unattractive conditions of service is negative contributor.
- Unsuccessful or incomplete Process Validation. High rates of batch rejections, excessive labour requirements,
- Increased cost of product etc.
- Incomplete Documentation.
- Product does not show specifications as intended.

- Delayed regulatory approval and/or product launch

Measure Elements In Technology Transfer Project Management[22]:

1. Project definition
2. Team development
3. Facility assessment
4. HS & E assessment
5. Skill set analysis / Training
6. Process development / approval
7. Analytical method transfer
8. Raw material component evaluations
9. Supply quality
10. Equipment selection and transfer
11. Process transfer
12. Verification
13. Data review
14. Conclusion/sign-off
15. Post transfer surveillance

Scale Up From R&D Laboratory To Production Scale[23,24,25]:

Pharmaceutical process scale up deals the procedures of transferring the results of R&D obtained on laboratory scale to the pilot plant and finally to production scale. Scale up is generally defined as the process of increasing the batch size. Scale up of a process can also be viewed as a procedure for applying the same process to different output volumes. There is a suitable difference between these to definitions: batch size enlargement does not always translate in to a size increase of the processing volumes. in mixing applications, scale up is indeed concerned with increasing the linear dimensions from the laboratory to the plant size. On the other hand, processes exist (e.g. Tableting) for which "scale up" simply means enlarging the output by increasing the speed.

In moving from R&D to production scale, it is sometimes essentials to have an intermediate batch scale. This is achieved at the so called pilot scale, which is defined as the manufacturing of drug product by a procedure fully representative off and simulating that used for full manufacturing scale. This scale also makes possible the production of enough a product for clinical testing. However, inserting an intermediate step between R&D and production scale does not in itself guarantee a smooth transition. A well-defined process may generate a perfect product in both the laboratory and pilot plant and then fail quality assurance tests in production.

Scale up can be done based in dimensional analysis. Dimensional analysis is a method for producing dimensionless number that completely characterizes the process. The analysis can be applied even when the equations governing the process are not known according to the theory of models two processes may be considers completely similar if the take place in similar geometrical place and if the all the dimensionless numbers necessary to described the process have the same numerical value. The scale up procedure, then, is a simple: express the process using complete set of dimensionless numbers, and try to match them at different scales. Dimension less numbers ,such as Reynolds and Froude numbers, are frequently used to described mixing processes. Scale up problems may require post approval changes that affect formulation compositions, site and manufacturing process or equipment's (From the regulatory stand point scale up and scale down are treated with the same degree of scrutiny) [26,27].

In a typical drug development cycle, once a set of clinical studies has been completed or an NDA/ANDA has been approved, it becomes very difficult to change the product or the process to accommodate specific production needs. Such need may include changes in batch size and manufacturing equipment's or process.

Post approvals changes in the size of a batch from the pilot scale to larger or smaller productions scales called for subssions of additional information in the application, with a specific requirement that the new

batches are to be produced using similar test requirements and in full compliance with CGMPs and the existing SOPs. Manufacturing changes may require new stability, dissolution, and in vivo bioequivalence testing[28].

Scale up of process may be done in such a way that all the problems that may arise production are identified and steps are taken to eliminate all problems to avoid extra cost of development and regulatory constraints[24].

Technology Transfer Documentation[22]:

Technology transfer documentation is generally interpreted as documents indicating contents of technology transfer for transferring and transferred parties. The raw data of the documents should be prepared and compiles according to purposed, and should be always readily available and traceable. For successful technology transfer, task assignments and responsibilities should be clarified, and acceptance criteria for the completion of technology transfer concerning individual technology to be transferred.

Quality assurance department should established confirmation process for all kinds of technology transfer documentation, and should check and approve the documentation. Technology transfer documentation are indicated as follows.

Organization for Technology Transfer:

One of the most significant elements for successful technology transfer is closed communication between transferring and transferred parties. Therefore, organization for technology transfer should be established and composed of both party members, roles, scope of responsibilities of each party should be clarified and adequate communication, and feedback of information should be ensured. It is desirable that this organization complies with GMP.

Research and Development Report:

To realize quality assurance at all stages from drug development to manufacturing, transfer to manufacturing, transfer of technical documents concerning product development or corresponding documents should be considered. The research and development report (development report) is a file of technical development, and the research and development department is in charge of its documentation. This report is an important file to indicate rationale for the quality design of drug substances and drug specifications and test methods. The development report before the approval inspection. Although the development report is not prerequisite for the application for approval, it can be used at the pre-approval inspection as valid document for the quality design of new drug. In addition, this report can be used as raw data in case of post-marketing technology transfer.

The following exemplifies information to be contained in the development report.

1. Historical data of pharmaceutical development of new drug substances and drug products at stages from early development phase to final application of approval
2. Raw materials and components
3. Synthetic route
4. Rational for dosage form & formula designs and design of manufacturing methods
5. Rational and change histories of important processes and control parameters
6. Quality Profiles of manufacturing batches (including stability data)
7. Specifications and test methods of drug substances, intermediates, drug products, raw materials, and components, and their rationale(validity of specification range of important tests such as contents impurities and dissolution, rational for selection of test methods, reagents and, columns, and traceability of raw data of those information)

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, and 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.

Technology Transfer Report:

It is to report the completion of technology transfer after data of action taken according to the technology plan is evaluated and the data is confirmed pursuant to the predetermined judgment criteria. Both transferring and transferred parties can document the technology transfer report; however, they should reach an agreement on its contents.

Verification of Results of Technology Transfer:

After the completion of technology transfer and before the start of manufacturing of the product, the transferring party should verify with appropriate methods such as product testing and audit that the product manufactured after the technology transfer meets the predetermined quality and should maintain records of the results.

Points of concern for post-marketing technology transfer:

1. While there are no fundamental difference in technology transfer between new developments report, which can be used as raw data.
2. In this case, development report needs not to be newly documented; however, it is strongly recommended that the file should be prepared including information of specified items.
3. This file can be used as reference file in case of regular inspection.

Conclusion:

Progressive pharmaceutical companies focus more attention to streamlining and optimizing their technology transfer process to ensure the rapid and successful introduction of new drug products to market. Technology transfer can be considered successful if a receiving unit can routinely reproduce the transferred product, process or method against a predefined set of specifications as agreed with a sending unit and/or a development unit. A dedicated technology transfer organization should be set up to facilitate and execute the process. Our nation should be build up with new technologies and its implementation. It is important to remove barriers to the free flow of science and technology.

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