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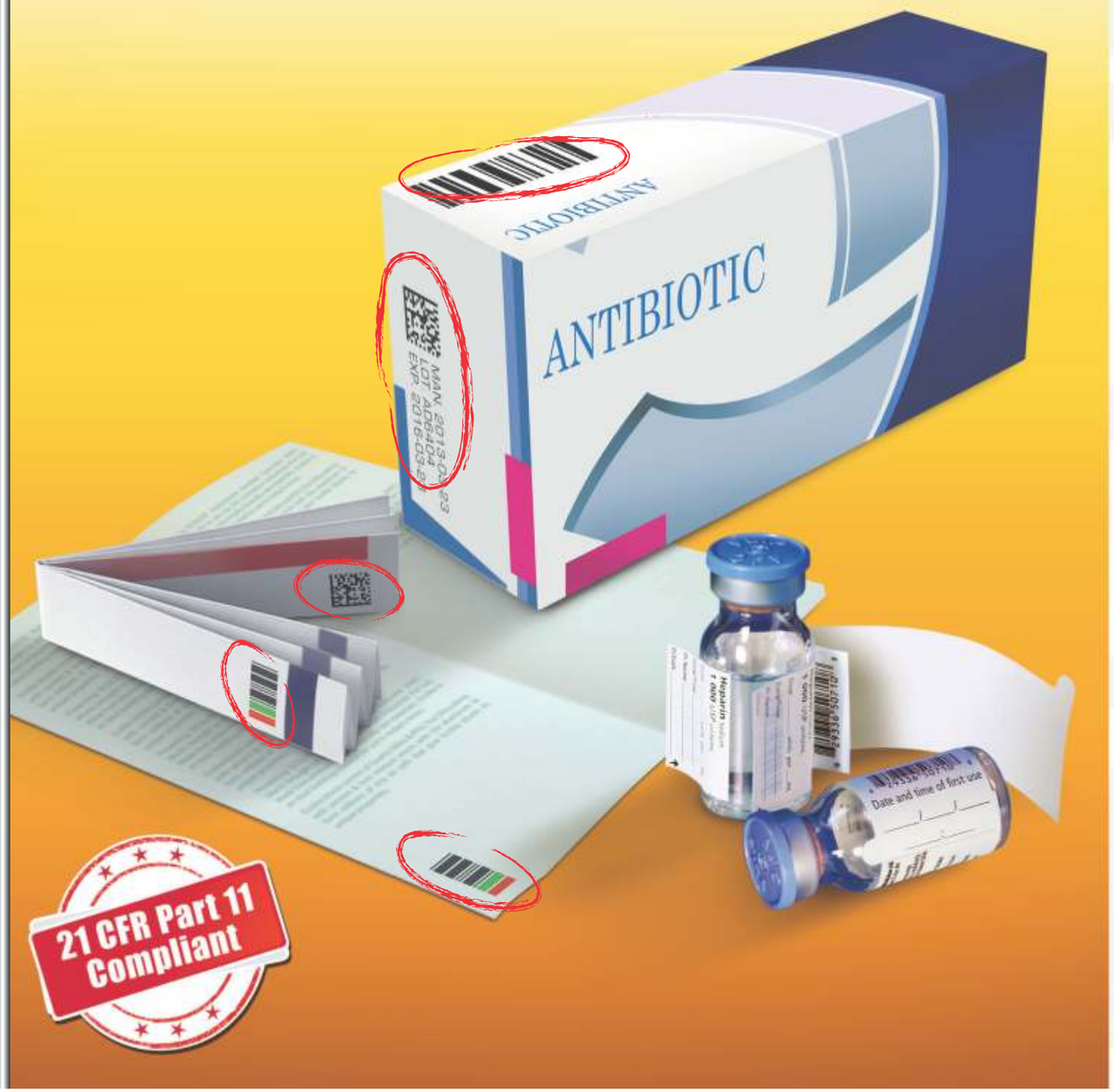

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CONTENTS

EDITORIAL

Rajesh Shah
Editor-in-Chief
PHARMA Pro&Pack

It is one of the most talked about subjects of recent times and yet there seems to be an air of apprehension surrounding it. Mention the two magical words of TECHNOLOGY TRANSFER and in all probability you will invite much attention. The Indian pharma industry is optimistic about technology transfer. Interesting it may sound but technology transfer is also a very complex subject having fallouts and repercussions on several fronts. First and foremost is what exactly defines technology transfer? Is it the tracing of the path all the way from scientific discovery to a useful product? Or is it a process for bridging an R&D process to commercial production? Or is it simply the transfer of technology which Indian companies – both pharma and pharma machinery manufacturers do not have and want it from the global players?

Besides how important is the issue of technology transfer for India's pharma industry as a whole and the pharma machinery manufacturers in particular? The industry also has to answer queries pertaining to which is the most important sector for technology transfer. Do the Indian pharma industry and the Indian pharma machinery manufacturers have the knowledge, facilities and the infrastructure to take in the world's most advanced product knowledge and manufacturing processes under technology transfer?

Perhaps this is the reason why we have decided to do a Cover Story on this very appealing subject of recent times. I hope you will indeed enjoy what we have brought specially for you.

I also take this opportunity to wish you & your family & all associates a very Happy, Prosperous, Progressive & Fruitful 2013!

PUBLISHER'S NOTE

Paresh Jhurmurwala
Publisher

GPE EXPO PVT. LTD.

2013 seems to have started on a rollicking note with the year almost chock-a-block full with exciting, interesting, knowledgeable & must attend programmes. But for the first issue of 2013, I will limit myself to the two big back-to-back events scheduled to kick off in Dhaka and Mumbai in the first quarter and the second quarters.

Taking off in February is the much awaited Asia Pharma Expo 2013 (APE2013), the three-day 10th international exhibition featuring the complete pharmaceutical manufacturing focusing the South Asian pharmaceutical industries scheduled during February 23rd to 25th, 2013 at the beautiful Bangabandhu International Conference Centre, Dhaka, Bangladesh. More than 480 companies from across 32 countries of the world will take part in APE2013.

The second important event coming up is the PHARMA Pro&Pack Expo 2013 (PPPE 2013) from April 24 to 26, 2013 at Mumbai. The exhibition having a special focus on promoting 'Brand INDIA' to both the Indian and world pharma industry is being jointly organised by the Indian Pharma Machinery Manufacturers' Association (IPMMA) and GPE Expo Pvt. Ltd.

So start packing your bags! See you in Dhaka and later in Aamchi Mumbai!

In this 2013 inaugural issue we have also brought for you a detailed profile of the Vietnam pharmaceutical industry.

I also wish all of you a Very Happy & Prosperous 2013! Also please do not forget to write to us with your valuable feedback. We will be more than happy to know what you feel about Pharma Pro & Pack. Also feel free to send us industry and trade updates.

Happy & Inspired Reading of this 2013 inaugural issue of Pharma Pro&Pack to All of You!

From drug discovery to product development - Technology Transfer leads the way

Technology transfer is a process to transfer information and technologies necessary to manufacture quality drug product consistently. In other words technology transfer is the process of taking an invention from its inception in a laboratory to a commercialised product. In pharmaceutical industry technology transfer means action 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. 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.

In the pharmaceutical industry, "technology transfer" refers to the processes that are needed for successful progress from drug discovery to product development to clinical trials to full-scale commercialisation or it is the process by which a developer of technology makes its technology available to commercial partner that will exploit the technology.

Technology transfer is defined as "The processes that are needed for successful progress from drug discovery to product development to clinical trials to full-scale commercialisation." In the pharmaceutical industry, "technology transfer" refers to the processes that are needed for successful progress from drug discovery to product development to clinical trials to full-scale commercialisation or it is the process by which a developer of technology makes its technology available to commercial partner that will exploit the technology. Investment in R&D is necessary but not a sufficient condition for economic growth. Productivity gains only result from the natural diffusion of innovation to the marketplace (technology transfer). Responsible departments for successful technology transfer of a product in pharmaceutical industry are R&D, Production, Engineering, QC and QA.

The transfer of technology is fundamentally a matter of the flow of human knowledge from one human being to another. The classic view of a flow from basic to applied technology is over simplification. E.g. Problems or insights arising at the production level give rise to new idea that contributes to fundamental basic advantage. Technology transfer is helpful to develop dosage forms in various ways as it provides efficiency in process, maintains quality of product, helps to achieve standardised 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. Technology transfer is both integral and critical to drug discovery and development for new medicinal products. The cost of product development raises during pilot scale-up and initial production batch i.e. the critical path for success is dependent on completion of technology transfer to the production site at an affordable cost.

Progressive pharmaceutical companies should pay more attention to streamlining and optimising their technology transfer process to ensure the rapid and successful introduction of new medicinal 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 organisation should be set up to facilitate and execute the process. To achieve this end, it is recommended that company should adopt a rigorous process to select its contract manufacturing partners to prevent issues in the future collaboration process. Provide strong support for scientific education and for basic research in areas that are important to the nation. It is important to remove barriers to the free flow of science and technology. Seeking global technological integration is far better for a world than political restrictions on the transfer of technology.

IMPORTANCE OF TECHNOLOGY TRANSFER

To elucidate necessary information to transfer technology of existing products between various manufacturing places and to exemplify specific procedures and points of concern for smooth technology transfer. 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 specifications and Good Manufacturing Practice requirement.

To elucidate necessary information to transfer technology from R&D to actual manufacturing by sorting out information obtained during R&D. Technology transfer is necessary to explain transfer of technology in a smooth manner of existing products between various manufacturing places.

Various Stages of Formulation Development:

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. Key stages of the process include data collection, data review, regulatory impact with particular emphasis on any change approvals, analytical validation, pilot or full-scale process batch, stability set down (if required).

For a typical research-based pharmaceutical company, drug discovery and development can be broken down into distinct stages. Typical process development work flow in pharmaceutical industry covers several phases. The first is the research phase which also covers quality design. The second phase is the development phase which covers research for factory

production, consistency between quality and specification, assurance of consistency through development and manufacturing, technology transfer from R&D to production. The third phase is the production phase which also covers validation & production, feedback from production and technology transfer of marketed products.

Appropriate transfer of manufacturing technologies (technology transfer) is important to upgrade drug quality as designed during R&D to be final product during manufacture as well as assure stable quality transferred for many reasons between contract giver and contract acceptor during manufacture.

To assure the drug quality, it is desire to make sure that the 5 W's and 1 H, that is What, When, 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 stake holders related to drug manufacturing.

Reasons for Technology Transfer

There may be many reasons why a developer of the technology might consider making its technology available to another person. One of the reasons for technology transfer is forming alliances with partners that can progress the development of the technology to take it to the market. The developer of the technology might have the resources to take the technology to particular state of development, such as up to animal studies and toxicology studies, but does not have the resources to take the technology through its clinical and regulatory phases, and must collaborate with another organisation to take it through these phases, and into the market.

Also important is forming alliances with partners with manufacturing capability. The developer of the technology may have taken the technology to a state of development so that it is near market ready, but does not have the clean room manufacturing capability or resources to manufacture the product, and must partner with another organisation that dose have that capability.

Alongwith manufacturing forming alliances with partners with marketing and distribution capability is also important. The developer of the technology may have fully developed the technology and even have obtained regulatory approvals and product registrations for the product to be sold, but it lacks the marketing and distribution channels to give it a marking capability and must collaborate with another organisation that does have that capability.

Exploitation in a different field of application is one more reason for technology transfer. The developer of the technology might be capable of exploiting the technology itself in the field of diagnostic applications, and may grant exploitation right to commercial partner for the exploitation of therapeutics applications. By transferring the technology for the use in another field of application to another person, the developer of the technology creates another income stream from the exploitation that takes place on that takes place in that other field.

Technology transfer is of importance in cases pertaining to no commercial capability. The developer of the technology may be research institute of a university, which does not have the capability to exploit commercially at all, and need to collaborate with another organisation that does have that capability. In the exploitation of pharmaceutical products, technology transfer by collaborating with this way to bring a pharmaceutical product to market is common feature of the industry.

Importance of Technology Transfer to Pharmaceutical Industry

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

Technology Transfer Process

The quality of design will be almost completed in phase II clinical study. Various standards for manufacturing and test will be established in process of reviewing factory production and phase III study to realise the quality of design, and the quality of design will be verified in various validation studies, and will be upgraded to be the quality of product and the actual production will be started. Technology transfer consists of action taken in these flows of development to realize through the quality as designed during the manufacture. Even if the production starts, the technology transfer will take place in process such as changes in manufacturing places.

The processes are broadly classified into the three categories Research Phase, Development Phase and Production Phase.

In the Research Phase the first aspect is quality design. For drug products, the quality design corresponds to so called pharmaceutical design-to-design properties and functions such as elimination of adverse reactions, improvement of efficacy, assurance of stability during distribution, and adding usefulness based on various data such as chemical and physical properties, efficacy, safety and stability obtained from preclinical studies.

For drug substance, the quality design is to determine starting materials and their reaction paths, and basic specification of the drug. In the Development Phase the first aspect is research for factory production. To manufacture drugs with qualities as designed, it is required to establish appropriate quality control method and manufacturing method, after detecting variability factors to secure stable quality in the scale-up validation that is performed to realize factory production of drug designed on the basis of result from small-scale experiments.

Technology transfer for consistency between quality and specification underlines the fact that when product specification is established on the basis of the quality of product determined in the above, it is required to verify that the specification adequately specifies the product quality. In short, the consistency between quality and specification is to ensure in the products specification that the quality predetermined in the quality design is assured as the manufacture quality, and the product satisfies the quality of design.

Technology transfer also gives assurance of consistency through development and manufacturing. To make developed product have indications as predetermined in clinical phases, the quality of design should be reproducible as the quality of product (assurance of consistency). For this purpose, the transferring party in charge of development should fully understand what kind of technical information is required by the transferred party in charge of manufacturing, and should establish an appropriate

evaluation method to determine whether a drug to be manufactured meets the quality of design.

Looking to the aspect of technology transfer from R&D to production, transfer of the technical information is necessary to realise manufacturing formula established in the above in the actual production facility. Technical information to be transfer should be compiled as R&D report.

In the third Production Phase, the first step is validation & production. Production is implemented after various validation studies verify that it is able to stably product based on transferred manufacturing formula. While the manufacturing facility accepting technology is responsible for validation, the research and development department transferring technology should take responsibility for validation such as performance qualification, cleaning validation, and process validation unique to subject drugs.

Now follows the feedback from production and technology transfer of marketed products. Technical information of developed products are obtained from data of a limited amount of batches, various standards have been established from the limited data, and quality evaluation method established in development phase in not always sufficient for factory production, it is highly desired to feed back and accumulate technical information obtained from repeated production, if necessary. In addition, it is important to appropriately modify various standards established before based on this information, and accountability and responsibility for design and manufacturing should be executed.

Also of paramount importance in the entire process is the documentation process of technology transfer. 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 compiled 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 establish confirmation process for all kinds of technology transfer documentation, and should check and approve the documentation. Technology transfer documentation basically involves six different steps.

Organisation for Technology Transfer:
One of the most significant elements for successful technology transfer is closed communication between transferring and transferred parties. Therefore, organisation 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 organisation complies with GMP.

Research and Development Report:
To realise 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 should be 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.

A development report should contain historical data of pharmaceutical development of new drug substances and drug products at stages from early development phase to final application of approval, raw materials and components, synthetic route, rational for dosage form & formula designs and design of manufacturing methods, rational and change histories of important processes and control parameters, quality profiles of manufacturing batches (including stability data), 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)

Product Specification File:
The product specification is to compile information, which enables the manufacture of the product, and to define specification, manufacturing and evaluations method of the product and its quality, and the transferring party is responsible for documenting the file. The product specification file should be reviewed at regular intervals, and incorporate all information obtained after the start of production of the product, and be revised as appropriate. For new products, the development report can be used as a part of product specification file.

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.

REASONS FOR TECHNOLOGY TRANSFER:
Lack of manufacturing capacity – The developer of technology may only have manufacturing equipment which is suitable for small scale operation, and must collaborate with another organization to do large scale manufacturing.
Lack of resources to launch product commercially - The original

inventor of technology may only have the resources to conduct early-stage research such as animal studies and toxicology study, but doesn't have the resources to take technology through its clinical and regulatory phases.

Lack of marketing and distribution capability - The developer of technology may have fully developed the technology and even have obtained regulatory approvals and product registrations, but it may not have the marketing and distribution channels.
Exploitation in a different field of application - Each partner may have only half of the solution i.e. the developer of the technology might be capable of exploiting the technology itself in the field of diagnostic applications and may grant exploitation right to commercial partner for the exploitation of therapeutics application.

FACTORS INFLUENCING TECHNOLOGY TRANSFER – DRIVERS FOR TECHNOLOGY TRANSFER

Good business and manufacturing practices – The company's success is primarily the result of its adoption of good business and manufacturing practices, particularly in the areas of product identification and formulation technology.

- Potential for competitive pricing –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 needs 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, market size and potential and a well developed national infrastructure of natural resources and transport.
- Transparent and efficient regulation – Pharmaceuticals are necessarily a high regulated industry, the regulatory function must be efficient and transparent for technology transfer to be economically viable.
- Opportunities for contingency supply – Multinational pharmaceutical 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, etc. could be applied profitably beyond the initial purpose.

Barriers of Technology Transfer

- Lack of efficiency – Automation of production processes to improve efficiency and lower costs.
- Low 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.

n Labour issues – The pharmaceutical sector demands relatively skilled labour. High labour turnover and absenteeism owing to unattractive conditions of service is negative contributor.

STEPS IN 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 excipient availability should be taken into account during the early phases of development of formulation so that successful scale up can be carried out.

The steps involved in technology transfer are as follows –
Development of technology by R&D (Research Phase)
(a) Design of procedure and selection of excipients by R&D – Selection of materials and design of procedures is developed by R&D on the basis of innovator product characteristics.
(b) Identification of specifications and quality by R&D – Quality of product should meet the specifications of an innovator product.
Technology transfer from R&D to production (Development Phase) – R&D provides technology transfer dossier (TTD) document to product development laboratory, which contains all information of formulation and drug product as follows -
(a) Master Formula Card (MFC) – Includes product name along with its strength, generic name, MFC number, page number, effective date, shelf life and market.
(b) Master Packing Card – Gives information about packaging type, material used for packaging, stability profile and shelf life of packaging.
(c) Master Formula – Describes formulation order and manufacturing instructions. (Process order and environment conditions)
(d) Specifications and Standard Test Procedures (STP'S) – Helps to know active ingredients and excipients profile, in-process parameters, product release specifications and finished product details.

Optimisation and Production (Production Phase)
(a) Validation Studies – Production is implemented after validation studies that can verify that process is able to stabilize the product based on transferred manufacturing formula. Manufacturing department accepting technology is responsible for validation and the R&D department transferring technology should take responsibility for validation such as performance qualification, cleaning and process validation.
(b) Scale up for production – Involves the transfer of technology during small scale development of the product and processes. It is essential to consider the production environment and system during development of process. Operators should concentrate on keeping their segment of the production process running smoothly.

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

(a) Development Report – The R&D report is a file of technical development, and 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 contains – (1) Data of pharmaceutical development of new drug substances and drug products at stages from early development phase to final application of approval. (2) Information of raw materials and components. (3) Design of manufacturing methods. (4) Change in histories of important processes and control parameters. (5) Specifications and test methods of drug substances. (6) Validity of specification range of important tests such as contents impurities and dissolution. (7) Verifications of results.

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

(c) Report – Completion of technology transfer is to be made once data are taken 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.

(d) 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.

POLICY APPROACHES THAT OVER COME BARRIERS IN TECHNOLOGY TRANSFER

Commercialising 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 – 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 nation's scientists.

National security issues and restrictions on exports of particular technology – International controls designed to protect national security and to prevent the proliferation of important technologies also restrict the flow of technologies.

Inadequate funding in important areas and possible treaties – There are areas of research of importance to the developing world that are being funded inadequately.

Cooperative research agreements – 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. The concept is mean to be nonzero sum in the sense that, like free trade in goods, free trade in scientific ideas benefits all, and such arrangements could be madebilaterally as well as multilaterally.

IF TECHNOLOGY TRANSFER ISN'T DONE RIGHT....

(1) Process Validation may be unsuccessful.
(2) Delayed regulatory approval and/or product launch.
(3) Flawed processing may result – high rate of batch rejections, costly schedule revisions and excessive labour requirements.
(4) Analytical methods cannot support production.
(5) Product does not perform as intended.

Issues in the Technology Transfer Process

Pharmaceutical and biotech industry is becoming increasingly competitive; many players are boosting their in-licensing activities, consolidating manufacturing networks and outsourcing production to less costly third-party manufacturers. All these strategic initiatives require effective technology transfer – smoothly moving technical knowledge processes and analytical requirements between the different parties involved. The issues to be focused are –

(a) Lack of repeatable and scalable business processes – Many organisations manage transfers as isolated, non strategic events involving little more than a procedural exchange of process documents between sending and receiving parties. But without repeatable and scalable processes companies are forced to reinvent the wheel each time technology changes hands. This leads to variety of inefficiencies such as suboptimal allocation of resources, higher development costs, quality and compliance issues.

(b) Lack of experience working with Contract Manufacturing Organisations – The key building blocks of this approach include

-- Rigorous selection process of contract manufacturing partner.

-- Clear and well documentation objectives and expectations.
-- Leading-edge process guide-lines and project management tools.
-- High-performance, dedicated cross functional technology transfer teams. PPP