CHAPTER 2

[Technology Development and Transfer]WHO Guidelines for Technology Transfer (TT):

1. Introduction:

- These guidelines are guiding principles
- Intended to serve as a flexible framework
- Focus on the quality aspects in line with WHO's mandate
- Transfer of processes to an alternative site occurs at some stage in the life cycle:

✓ Development

✓ Scale-up

✓ Manufacturing

✓ Production & launch

✓ Post-approval phase

2. Definition of Transfer of Technology:

- A logical procedure.
- That controls the transfer of any process together with its documentation & professionalexpertise.
- Between development & manufacture or between manufacture sites.

3. Requirements of Transfer of Technology:

- Documented, planned approach.
- Trained & Knowledgeable personnel.
- Compliant quality system.
- Documentation of data: Development, production & Quality control.
- Usually there is a Sending unit (SU), A Receiving unit & Unit managing the process, whichmay or may not be a separate entity.

4. Legal & Economic implications:

- Intellectual property rights
- Royalties
- Pricing
- Conflict of interest
- Confidentiality

5. Technology Transfer Protocol:

The protocol should include:

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

6. Quality Risk Management (QRM):

- Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product across the product life cycle.
- The evaluation of the risk to quality should be based scientific knowledge and ultimately linked to the protection of the patient.
- From a GMP point of view, we are only concerned with risks associated with quality, safety & efficacy.

7. Transfer from Research and Development to Production (APIs, Excipients, Process, Packaging and Cleaning):

APIs and Excipients:

- APIs and Excipients to be used at the RU should be consistent with materials used atthe SU.

Process:

- The RU should be able to accommodate the intended production capacity.
- Consideration should be given to the technical expertise, site technology & site capabilities for the RU.

  APIs and Excipients to be used at the RU should be consistent with materials used atthe SU.
- Any properties, which are likely to influence the process or product, should be identified and characterized.
- The SU should provide a detailed characterization of the product, including its qualitative & quantitative composition.
- The SU should provide any information on the history of process development.
- The SU should provide information on health, safety & environmental issues.
- The SU should provide information on current processing & testing.

Packaging:

- Information on packaging to be transferred from the SU to the RU includes:

✓ Specifications for a suitable container or closure system.

✓ Any relevant additional information on design, packing, processing or labelingrequirements.

✓ Tamper-evident and anti-counterfeiting measures needed at the RU.

Cleaning:

- During the manufacturing process, pharmaceutical products and APIs can be contaminated by other pharmaceutical products or APIs if the plant is processing different products.
- To minimize the risk of contamination and cross-contamination, operator exposure & environmental effects, adequate cleaning procedures are essential.
- Cleaning procedures and their validation are site-specific.
- The SU should provide information on cleaning to minimize cross-contamination.

8 Analytical Method Transfer:

- A protocol defining the steps should be prepared for transfer of analytical methods.
- The analytical methods transfer protocol should include a description of the objective, scope and responsibilities of the SU and the RU.
- A specification of materials and methods; the experimental design and acceptance criteria.
- Documentation
- Procedure for the handling of deviations.
- Details of reference samples.

9. Technology Transfer Agencies in India:

APCTT [ASIAN & PACIFIC CENTRE FOR TRANSFER OF TECHNOLOGY]:

- It is a United Nations Regional Institution under the Economic & Social Commission for Asia and the Pacific (ESCAP).
- Established in 1977 in Bangalore, India.
- In 1993, the centre moved to New Delhi, India.
- APCTT promotes transfer of technology to and from small- and medium –scale enterprises (SMEs) in Asia and the Pacific.
- APCTT implements developing projects funded by international donors.
- APCTT undertakes consultancy assignments in various technology transfer areas.
- The objective of the APCTT is to strengthen the technology transfer capabilities in the region & to facilitate import/export of environmentally sound technologies to/from the member countries.

NRDC [NATIONAL RESEARCH DEVELOPMENT CORPORATION]:

- The NRDC was a non departmental government body established by the British Government to transfer technology from the **public sector** to the **private sector**.
- The NRDC was established in India in 1953 to develop & promote technologies developed at various R & D institutions.
- In 1981, the NRDC was combined with the National Enterprise Board to form British Technology Group.
- Typically the NRDC would patent the product for commercial exploitation and earn royalties as private sector companies generated sales from those products.

TIFAC :

- TIFAC is an autonomous organization set up in 1988 under the Department of Science & Technology.
- The objective of TIFAC is to look ahead in technology domain, assess the technology trajectories, and support innovation in selected areas of national importance.

- TIFAC embarked upon the major task of formulating a **Technology Vision** for the countryin various emerging technology areas.

BCIL [BIOTECH CONSORTIUM INDIA LIMITED]:

- BCIL, New Delhi was incorporated as public limited company in 1990 under the Company Act, 1956.
- BCIL's major functions include the development and transfer of for the commercialization of biotechnology products, project consultancy, biosafety awareness & human resource development.
- BCIL has been successfully managing several Flagship schemes & programs of the department of biotechnology.

TBSE [TECHNOLOGY BUREAU FOR SMALL ENTERPRISES]:

- TBSE is a platform for MSMEs to tap opportunities at the global level for the acquisition of technology or establishing business collaboration.
- TBSE is a result of the cooperative initiative of the United Nations Asian & Pacific Centre for transfer of Technology (APCTT) and Small Industries Development Bank of India.
- TBSE offers a professionally managed system for the reasons of technology and collaboration exploration.
- TBSE helps in building of confidence between potential partners.
- Provides an opportunity to global technology market through the process of networking.
- Exclusive mechanism for the arrangement of technology & finance.

Learning Outcome:

To understand the process of Technology Transfer from Lab scale to Commercial scale.

Important questions:

[Two marks Questions]

1. What is APCTT?
2. What is NRDC?
3. What is TIFAC?
4. What is BCIL?
5. What is TBSE?

[Five marks Questions]

1. What are the objectives of technology transfer?
2. Explain technology transfer protocol in detail.
3. Discuss quality risk management in detail.
4. Discuss the analytical method transfer during technology transfer.
5. Discuss the various problems during technology transfer.

[Ten marks Questions]

1. Explain in detail various technology transfer agencies in India.
2. Discuss in detail process, packaging and cleaning issues during technology transfer.
3. Explain technology transfer considerations regarding APIs, excipients and finishedproducts.