

## UNIT – 2

### Technology Development and Transfer:

#### Terminology:

- **Technology Development:** The process of creating new or improved technologies through research and development (R&D).
- **Technology Transfer (TT):** The process of conveying and implementing developed technologies from one entity to another.

#### WHO Guidelines for Technology Transfer (TT):

##### 1. Technology Transfer Protocol:

- A detailed plan outlining the entire technology transfer process.
- Covers R&D, manufacturing, quality control, and regulatory aspects.

##### 2. Quality Risk Management:

- Identifies, assesses, and controls risks associated with technology transfer.
- Ensures product quality, safety, and efficacy.

##### 3. Transfer from R&D to Production:

- **Process Transfer:** Ensures the successful transition of a developed process from R&D to commercial production.
- **Packaging and Cleaning Transfer:** Includes transfer of packaging and cleaning processes.

##### 4. Granularity of TT Process:

- **API (Active Pharmaceutical Ingredient):** Transfer of processes related to the production of key pharmaceutical ingredients.
- **Excipients:** Transfer of knowledge and processes related to non-active ingredients.
- **Finished Products:** Transfer of formulations and manufacturing processes.
- **Packaging Materials:** Transfer of processes related to packaging.

##### 5. Documentation:

- **Technology Transfer Agreement:** Outlines roles, responsibilities, and terms.
- **Master Batch Records:** Detailed instructions for manufacturing.
- **Standard Operating Procedures (SOPs):** Documented procedures for various processes.

##### 6. Premises and Equipment, Qualification, and Validation:

- Ensures facilities and equipment meet quality standards.

- **Qualification:** Verification that equipment performs as intended.
- **Validation:** Ensures processes consistently produce the desired results.

#### 7. Quality Control and Analytical Method Transfer:

- Transfer of analytical methods to ensure consistent product quality.
- Quality control measures to monitor and verify product quality.

#### 8. Approved Regulatory Bodies and Agencies:

- Ensures compliance with regulatory requirements.
- Collaborates with regulatory bodies to obtain approvals.

#### 9. Commercialization - Practical Aspects and Problems (Case Studies):

- **Practical Aspects:** Consideration of market demands, scalability, and production costs.
- **Problems:** Unforeseen technical or regulatory challenges.

#### 10. TT Agencies in India:

- **APCTD (Andhra Pradesh Centre for Technology Development):** Facilitates technology transfer and commercialization.
- **NRDC (National Research Development Corporation):** Promotes technology transfer and commercialization of technologies.
- **TIFAC (Technology Information, Forecasting and Assessment Council):** Focuses on technology forecasting and assessment.
- **BCIL (Biotech Consortium India Limited):** Promotes biotechnology-related technology transfer.
- **TBSE/SIDBI (Technology Bureau for Small Enterprises/Small Industries Development Bank of India):** Facilitates technology transfer for small enterprises.

#### 11. TT-related Documentation:

- **Confidentiality Agreement:** Protects proprietary information during technology transfer discussions.
- **Licensing:** Grants permission for the use of intellectual property.
- **Memorandum of Understanding (MoUs):** Formalizes the agreement between parties.
- **Legal Issues:** Addressing intellectual property rights, liability, and dispute resolution.

Technology transfer is a complex process that requires meticulous planning, documentation, and collaboration. Adherence to guidelines and the involvement of regulatory bodies are critical for ensuring the successful and compliant transfer of technologies.