UNIT –2- TECHNOLOGY DEVELOPMENT & TRANSFER

POINTS TO BE COVERED IN THIS TOPIC

- WHO GUIDELINES FOR TECHNOLOGY TRANSFER (TT)
  - ❖ Terminology
  - ❖ Technology Transfer Protocol
- QUALITY RISK MANAGEMENT
- TRANSFER FROM R & D TO PRODUCTION (PROCESS, PACKAGING AND CLEANING)
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UNIT -2- TECHNOLOGY DEVELOPMENT & TRANSFER

POINTS TO BE COVERED IN THIS TOPIC

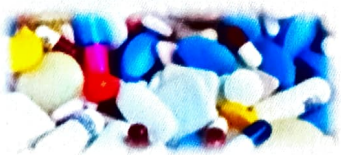
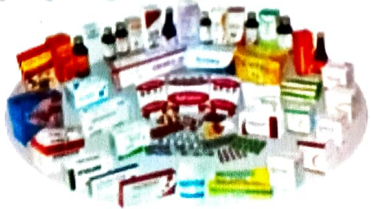
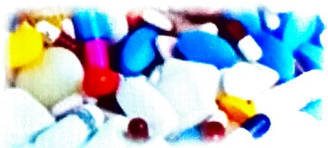
- COMMERCIALIZATION- PRACTICAL ASPECTS AND PROBLEMS
- TT AGENCIES IN INDIA –APCTD, NRDC, TIFAC, BCIL, TBSE/ SIDBI
- TT RELATED DOCUMENTATION - CONFIDENTIALITY AGREEMENT, LICENSING, MoUs, LEGAL ISSUES.

INTRODUCTION

- The present market condition is defined as "A age of competition in terms of quality and low price of products."
- In order to sustain in market companies are more aggressively formulating their policies on **research** and **development** and market competitiveness.
- In this process, Various events like merger, consolidation, splitting of business etc. are taking place.
- Therefore, companies either go for in house R & D or purchase Technology form others inside the country or from abroad.
- Pharma industry is characterized with wide range of **innovative products** with changing demand.
- So, The standard protocol for Transfer to Technology from Research to Industry needed.

WHO GUIDELINES FOR TECHNOLOGY TRANSFER (TT)

- The World Health Organization (WHO) is a specialized agency of the United Nations looking after issues of **international public health.**
- It was established on **7 April 1948**. Its headquarter is in **Geneva Switzerland.**
- The WHO is a member of the **United Nations development group**. This draught text was subsequently prepared by **Mr. John startup** United Kingdom and by **Dr. Monika Zweygarth** South Africa.
- The document was then discussed during the consultation on WHO guidelines for medicine, quality assurance quality control laboratories and transfer of Technology on **27- 31 July 2009** and a revision prepared.
- The WHO Expert Committee on Specifications for Pharmaceutical Preparation, therefore, recommended in its 42nd report that WHO address this issue through preparation of WHO guidelines in this area.

❖ TERMINOLOGY

- **Acceptance criteria: Measurable** terms under which a test result will be considered acceptable.
- **Bracketing**: An **experimental design** to taste only the extreme of, for example dosage strength. The design assume that the extremes will be **representative** of all the samples between the **extremes**.
- **Change control (CC):** A **formal system** by which **qualified representatives** of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a **validated state.**
- **Critical**: Having the potential to impact to **product quality** or **performance** in a significant way.
- **Critical control point (CCP):** A step at which control can be **applied** and is essential to prevent or eliminate a **pharmaceutical quality hazard** or reduced it to an **acceptable level.**
- **Corrective action**: Any action to be taken when the results of monitoring at a **critical control point** indicate a loss of control.
- **Quality risk management (QRM)**: It is a systematic process for the **assessment, control, communication** and **review of risk** to the quality of the pharmaceutical product across the product life cycle.
- **Inter company transfer:** Transfer of technology between sites of **different companies.**
- **Intra company transfer:** Transfer of Technology between sites of the **same group of companies.**
- **Inter site transfer**: Transfer of Technology between **sites of** same **company.**
- **In process control (IPC):** Checks Preformed during production in order to **monitor** and if necessary to adjust to the process to ensure that the **product confirms** to its specifications for a stop the control of the **environment** or **equipment** may also be regarded as a part of in process control.

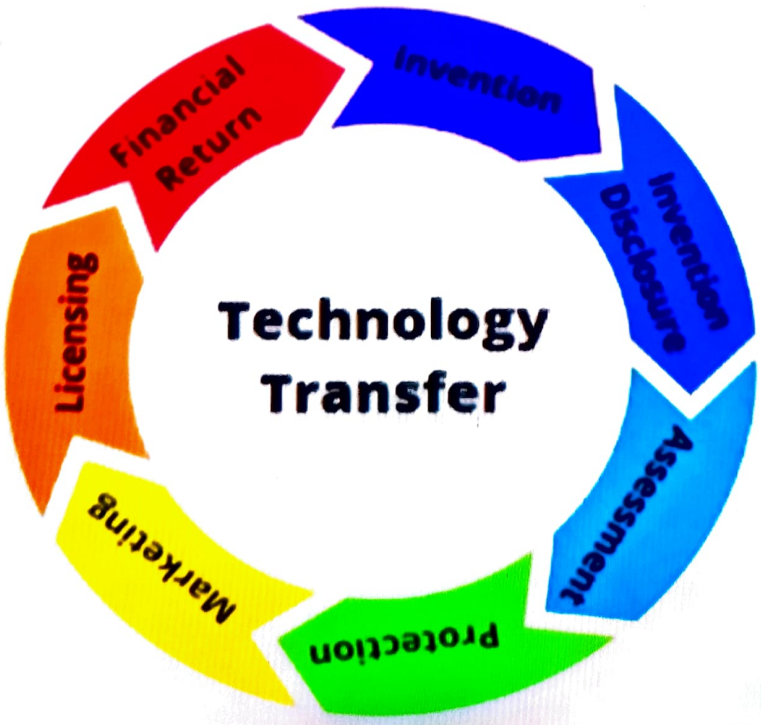
- **Qualification**: Action of **proving** and **documenting** that any premises, system and equipment's are properly installed and/or working correctly and lead to the expected results.
- **Installation Qualification (IQ):** The performance of tests to ensure that the installation such as machines **measuring devices utilities** and **manufacturing areas** used in manufacturing process appropriately selected and correctly installed and operate in accordance with established specifications.
- **Operational Qualification (OQ):** **Documented verification** that the system or subsystem performs as intended overall anticipated operating ranges.
- **Performance Qualification (PQ):** Documented verification that the **equipment** or **system** operates consistently and gives **reproducibility** within defined **specifications** and **parameters** for **prolonged periods.**
- **Standard operating procedures (SOP):** An **authorized written procedure** giving instructions for performing operations not necessarily specific to a given product or material. For example Operation of equipment, maintenance and cleaning, validation meaning of premises and environment control sampling and inspection) certain SOP may be used to supplement product specific master and batch production documentation.
- **Drug Master File (DMF):** Detailed information concerning a specific **facility**, **Process** or **Product** submitted to the **Drug Regulatory Authority,** Intended for the incorporation into the **application** for marketing authorization.

❖ TECHNOLOGY TRANSFER PROTOCOL

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

1.	Objective
2.	Scope
3.	Key personnel and their responsibilities

4.	Objective
5.	Scope
6.	Key personnel and their responsibilities
7.	a parallel comparison of materials, methods and equipment;
8.	the transfer stages with documented evidence that each critical stage has been
9.	satisfactorily accomplished before the next commences;
10.	identification of critical control points;
11.	experimental design and acceptance criteria for analytical methods;
12.	information on trial production batches, qualification batches and process validation
13.	change control for any process deviations encountered;
14.	assessment of end-product;
15.	arrangements for keeping retention samples of active ingredients, intermediates and finished products, and information on reference substances where applicable
16.	Conclusion, including signed-off approval by project manager.



QUALITY RISK MANAGEMENT

❖ INTRODUCTION

- Quality risk management is a **systematic process** for the assessment **control communication** and **review of risk** to the quality of the medicinal product across the product life cycle.
- Quality risk management activities are usually undertaken by **interdisciplinary teams** as **quality unit, business development, engineering, regulatory affairs, production, operations, sales** and **marketing, legal, statics** and **clinical** in addition to individuals who are knowledgeable about the quality risk management process.
- Quality risk management is a process that supports **science based** and **practical decisions** when integrated into quality system.

❖ BENEFITS OF QRM:

1. Effective quality risk management can facilitate better and more **informed decisions** and can provide **regulator's** with greater **Assurance** of a company's ability to deal with **potential risks.**
2. In addition quality risk management can facilitate better use of resources by all parties.
3. Quality risk management should be integrated into existing applications and **documented appropriately.**

❖ PRINCIPLES OF QUALITY RISK MANAGEMENT

- Two primary principles of quality risk management are:
  - ✓ The **evaluation of the risk to quality** should be based on scientific knowledge and ultimately link to the protection of the patient.
  - ✓ The **level of effort, formality and documentation** of the quality risk management process should be commensurate with the level of risk.

❖ TERMINOLOGY

S.NO	TERM	DEFINATIONS
1.	Harm	Damage to health, including the damage that can occur from loss of product quality or availability.
2.	Hazard	The potential source of harm (ISO/IEC Guide 51).
3.	Detectability	The ability to discover or determine the existence, presence, or fact of a hazard.
4.	Decision Maker	Person(s) with the competence and authority to make appropriate and timely quality risk management decisions.
5.	Product Lifecycle	All phases in the life of the product from the initial development through marketing until the product's discontinuation
6.	Quality	The degree to which a set of inherent properties of a product, system or process fulfills requirements (see ICH Q6A definition specifically for "quality" of drug substance and drug (medicinal) products.)
7.	Quality System	The sum of all aspects of a system that implements quality policy and ensures that quality objectives are met.
8.	Risk	The combination of the probability of occurrence of harm and the severity of that harm
9.	Risk Acceptance	The decision to accept risk
10.	Risk Analysis	The estimation of the risk associated with the identified hazards.

S.NO	TERM	DEFINATIONS
11.	Risk Assessment	A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
12.	Risk Communication	The sharing of information about risk and risk management between the decision maker and other stakeholders.
13.	Risk Control	Actions implementing risk management decisions.
14.	Severity	A measure of the possible consequences of a hazard.

TRANSFER FROM R & D TO PRODUCTION (Process, Packaging and Cleaning)

- This is the most Critical and Important part of technology transfer document. Following Points must be considered while drafting an agreement-

1. It should be established at the outset whether the intention is to perform single batch manufacture, continuous production or campaigns and whether the production unit can accommodate the intended production capacity.
2. Consideration should be given to the level and depth of detail to be transferred to support Production and any further development or process optimization at the production unit as intended under the transfer Project plan.
3. Consideration should be given to the technical expertise, site technology and site capabilities. For the production unit. R&D unit should identify all the process issue and make it operational at the production unit.

4. The R&D unit and Production unit should jointly develop a **protocol for the transfer** of relevant Information related to the process under consideration from the **R&D unit** to the **production unit**, As well as the **development** of **comparable process** at the **production unit.**

GRANULARITY OF TT PROCESS (API, EXCIPIENTS, FINISHED PRODUCTS,PACAGING MATERIALS)

Granularity of Technology Transfer Process deals with details of data regarding :

- Starting materials
- Active Pharmaceutical ingredients
- Excipients
- Process
- Finished Product
- Packing Material

1. STARTING MATERIALS

- The specifications of the starting materials (APIs and excipients) to be used at the RU should be consistent with **reference batches (development batches, bio-batches or batches manufactured at the SU).** Any properties which are likely to influence the process or product should be **identified** and **characterized.**

2. ACTIVE PHARMACEUTICAL INGREDIENTS (API)

- The SU should provide the **drug master file (DMF)** and any relevant additional information on the API to the RU to be checked against the specifications of the API. The following information should be provided:

The following information should be provided:

- **Manufacturer**
- **Flow chart of synthesis pathway**
- **Definitive physical form of the API (including photomicrographs and other relevant data) and any polymorphic and solvate forms**
- **Solubility profile**

- Partition coefficient (including the method of determination)
- Intrinsic dissolution rate (including the method of determination)
- Particle size and distribution
- Bulk physical properties, including data on bulk and tap density, surface area and porosity as appropriate;
- Water content and determination of hygroscopicity, including water activity data and special handling requirements;
- Special considerations with implications for storage and/or handling, e.g. safety and
- Environmental factors and sensitivity to heat, light or moisture.

3. EXCIPIENTS

- An excipients is substance like sugar, gum etc. used to prepare drug so as to make it **suitable to administer.**
- These excipients have a **potential impact** on the final product.
- Their specifications as well as the Drug Master File (DMF) or equivalent information should be made available by the **sending unit (SU)** for transfer to the **production site.**
- The following information should be provided for all types of **excipients**:
  - ✓ **Description** of functionality, with justification for inclusion of any antioxidant
  - ✓ **Preservative** or any **excipients** above recommended guideline
  - ✓ **Manufacturer**
  - ✓ **Specifications** ,i.e., monographs and additional information that may affect product processing or quality for compendia excipients, or a complete listing of specifications, including analytical methods and justification for release limits for non-compendial excipients.
  - ✓ **Special considerations** with implications for storage and/or handling, including but not limited to safety and environmental factors (e.g. as specified in material safety data sheets) and sensitivity to heat, light or moisture solubility

4. FINISHED PRODUCTS

- Depending on the type of dosage form, the SU should provide relevant information on physical properties of excipients to the RU, including:

  - ✓ **Definitive form** (for solid and inhaled dosage forms)
  - ✓ **Solubility profile** (for solid, inhaled and transdermal dosage forms)
  - ✓ **Partition coefficient**, including the method of determination (for transdermal dosage forms)
  - ✓ **Intrinsic dissolution rate**, including the method of determination (for transdermal dosage forms)
  - ✓ **Particle size and distribution**, including the method of determination (for solid, inhaled and transdermal dosage forms)
  - ✓ **Bulk physical properties**, including data on bulk and tap density, surface area and porosity as appropriate (for solid and inhaled dosage forms)
  - ✓ **Compaction properties** (for solid dosage forms)
  - ✓ **Melting point range** (for semi-solid/topical dosage forms)
  - ✓ **pH range** (for parenteral, semi-solid/topical, liquid and transdermal dosage forms)
  - ✓ **Ionic strength** (for parenteral dosage forms)
  - ✓ **Specific density/gravity** (for parenteral, semi-solid/topical, liquid and transdermal dosage forms)
  - ✓ **Viscosity and/or viscoelasticity** (for parenteral, semi-solid/topical, liquid and transdermal dosage forms)
  - ✓ **Osmolarity** (for parenteral dosage forms)
  - ✓ **Water content and determination of hygroscopicity**, including water activity data
  - ✓ **Special handling requirements** (for solid and inhaled dosage forms)
  - ✓ **Moisture content range** (for parenteral, semi-solid/topical, liquid and transdermal dosage forms)
  - ✓ **Microbiological considerations** in accordance with regional pharmacopeial requirements (for parenteral, semi-solid/topical, liquid, inhaled and transdermal dosage forms)

5. PACKAGING

- Information on Packaging to be transferred from the **SU** to the **RU** include specifications for a **suitable container/closure system**, as well as any relevant **additional information** on design, packing, processing or labeling requirements needed for qualification of packaging components at the RU.
- For quality control testing of **packaging components**, **specifications** should be provided for drawings, artwork, material.

DOCUMENTATION

- An **authorized technology transfer document**, for example, a Master Plan (or Technology Transfer Protocol) should list the intended sequential phases and activities of the transfer, where appropriate.
- The document should include the following:

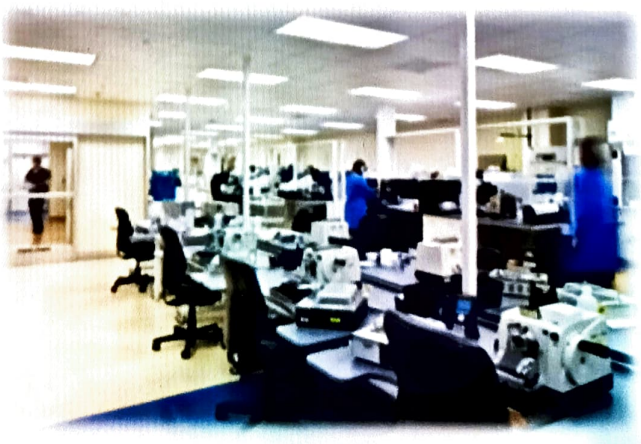
1.	Title
2.	Objective
3.	Scope
4.	Name and addresses of the SU and RU
5.	Key personnel and their responsibilities
6.	Phases of the project including key activities, deliverables and the associated accountabilities
7.	Approximate timing of key activities/deliverables including the timing of trial production batches and validation batches
8.	Reference to qualification/validation master plans relevant to the process being transferred
9.	Reference to gap assessments and risk assessments
10.	Acceptance criteria for a successful transfer

11.	A parallel comparison of premises, equipment, instruments, materials, procedures, and methods for the transfer under consideration.

PREMISES AND EQUIPMENT

❖ PREMISES

- The SU should provide information to the RU on the layout, construction and finish of all buildings and services (heating, ventilation and air-conditioning (HVAC), temperature, relative humidity, water, power, compressed air).
- Quality control laboratories should be equipped and capable of testing all APIs, excipients, intermediate and finished products, packaging components and cleaning validation samples.
- Buildings intended for production of a Highly sensitizing nature (e.g. penicillin's and cytotoxic materials) should be dedicated for this purpose and located in a different facility from other production units, Health, safety and environmental issues, including waste management, emergency.
- Planning, minimization of operator exposure and environmental impact, should be addressed at the RU in compliance with any regulatory or company-developed rules, regulations and limits. buildings and services at the RU should be capable of accommodating the product,
- Process or method under transfer to the agreed quality standard and production volume in compliance with GMP.

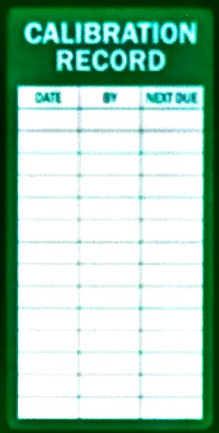


❖ EQUIPMENT'S

- The SU should provide a list of **equipment**, makes and models involved in the **manufacture**, **filling**, **packing** and/or **control of the product,** process or method to be transferred, together with existing qualification and validation documentation.

Relevant documentation may include:

- ✓ **Drawings**
- ✓ **Manuals**
- ✓ **Maintenance logs**
- ✓ **Calibration logs**
- ✓ **SOPs (e.g. equipment set up, operation, cleaning, maintenance, calibration, storage).**



- The RU should review the **information provided** by the SU together with its own inventory list including the **qualification status (IQ, OQ, PQ)** of all **equipment** and **systems**, and perform a **side-by- side comparison** of equipment at the two sites in terms of their functionality, makes, models and qualification status.
- Based on the side-by-side comparison, the RU should perform a **gap analysis** to identify requirements for adaptation of existing equipment.
- GMP requirements should be satisfied, and intended production volumes and batch sizes (e.g. same, scaled-up or campaign) should be considered.
- Factors to be compared include:
  - ✓ Minimum and maximum capacity
  - ✓ Material of construction
  - ✓ Critical operating parameters
  - ✓ Critical equipment components (e.g. filters, screens, temperature/pressure sensors)
  - ✓ Range of intended use.

QUALIFICATION AND VALIDATION

- The extent of qualification and validation to be performed should be determined on the basis of **risk management principles**, taking into account the **product's life cycle phase.**
- Equipment and instruments should be **qualified** and **calibrated** before using them to support the technology transfer activities.
- Process validation should be done according to guidelines as published in **current WHO Technical Report Series.**
- Production processes and analytical procedures should be appropriately transferred to the **RU following documented procedures**. Where validation data exist, these should be included in the transfer.
- For cleaning procedures, development and validation should be done in accordance with the guidelines as published in **current WHO Technical Report Series.**
- Points to consider when using HBEL in cleaning validation should be taken into account in establishing **cleaning procedures, cleanability studies** and **setting acceptance limits.**
- **Analytical procedures** should be validated or verified according to the guidelines as published in current WHO Technical Report Series.
- Qualification and validation procedures, protocols, data and results should be **appropriately recorded**. The documents should be retained as defined in procedures.

QUALITY CONTROL : ANALYTICAL METHOD TRANSFER

- Analytical procedures used to test **pharmaceutical products, starting materials, packaging components** and **cleaning** (residue) **samples**, if applicable, should be implemented at the **testing laboratory** before the testing of samples for process validation studies is performed by the RU.
- The transfer of the **analytical procedure** may be accomplished by several approaches such as **confirmation testing, comparability testing** between SU and RU results, **co-validation between laboratories**, or through a "**paper-based knowledge" transfer.**

- The analytical procedures transfer protocol should include:

1.	A description of the objective, scope and responsibilities of the SU and the RU
2.	A specification of materials and methods
3.	The experimental design and acceptance criteria
4.	Documentation
5.	Procedure for the handling of deviations
6.	Details of test samples

The SU's responsibilities for the transfer of analytical procedures typically are to:	
1.	Provide method-specific training for analysts and other QC staff, if required
2.	Assist in analysis of QC testing results
3.	Define all procedures to be transferred for testing a given product, starting material or cleaning sample
4.	Define experimental design, sampling methods and acceptance criteria
5.	Provide any validation reports for procedures under transfer including proof of their robustness
6.	Provide details of the equipment used, as necessary (part of validation report, if available) and any standard test samples
7.	Provide approved procedures used in testing
8.	Review and approve transfer reports

- The appropriate training should be provided and all **training activities** and **outcomes should be documented.**
- Reference should be made to **compendial monographs** such as The **International Pharmacopoeia, European Pharmacopoeia, British Pharmacopoeia and United States Pharmacopeia, where these are relevant.**

The RU should exercise its responsibility to:	
1.	Review analytical procedures provided by the SU, and formally agree on acceptance criteria before execution of the transfer protocol
2.	Ensure that adequately trained and experienced personnel are in place for analytical testing
3.	Execute the transfer protocol
4.	Provide a documentation system capable of recording receipt and testing of samples

APPROVED REGULATORY BODIES AND AGENCIES

1. THE CENTRAL DRUG STANDARDS AND CONTROL ORGANIZATION (CDSCO)

- In India, the Central Drugs Standard Control Organization (CDSCO) is the **main regulatory body, Headquartered in New Delhi** currently regulating import, sale and manufacture of medical devices.
- The CDSCO lays down **standards of drugs, cosmetics, diagnostics** and **devices and issues licenses to drug manufacturers and importers**.
- It also lays down **regulatory measures, amendments to Acts** and **Rules** and regulates market authorization of new drugs, clinical research in India and standards of imported drugs etc.

2. NATIONAL INSTITUTE OF HEALTH AND FAMILY WELFARE (NIHFW)

- NIHFW is an **Apex Technical Institute, funded by Ministry of Health and Family Welfare**, for promotion of health and family welfare programmers in the country through education, training, research, evaluation, consultancy and specialized services.
- The **NIHFW was established on March 9, 1977** by a merger of the National Institute of Health Administration and Education (NIHAE) with the National Institute of Family Planning (NIFP).

3. DRUG TECHNICAL ADVISORY BOARD (DTAB)

- The Central government constitute a board to advice the central government and the state governments on technical matters arising out of the administration of D & C, Act 1940. it advices matter related to drugs.

DTAB
Drugs Technical Advisory Board

4. CENTRAL DRUG TESTING LABORATORY (CDTL)

- The Central drug laboratory, Kolkata is national statutory laboratory of the government of India for quality control of drug and cosmetic and established under the **D & C act 1940**
- It is the oldest quality control laboratory of the drug control authorities in India
- Functions under the director general of health services in the ministry of health and family welfare

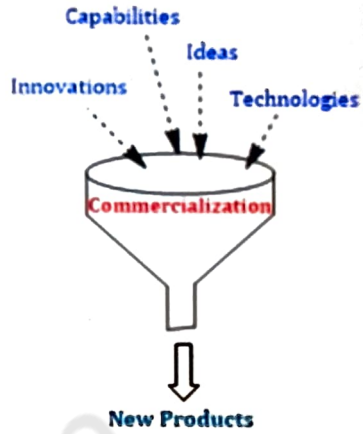
5. USFDA

- The Food and drug administration (FDA) is an agency within the U.S department of health services.
- The Food & Drug modernization act states that the FDA has 4 roles:
  - ✓ To promote health by reviewing research and approving new products
  - ✓ To ensure foods and drugs are safe and properly labelled
  - ✓ To work with other nations to " reduce the burden of regulation"
  - ✓ To cooperate with scientific experts and consumers to effectively carry out these obligations.

COMMERCIALIZATION –PRACTICAL ASPECTS AND PROBLEMS (CASE STUDIES)

❖ COMMERCIALIZATION

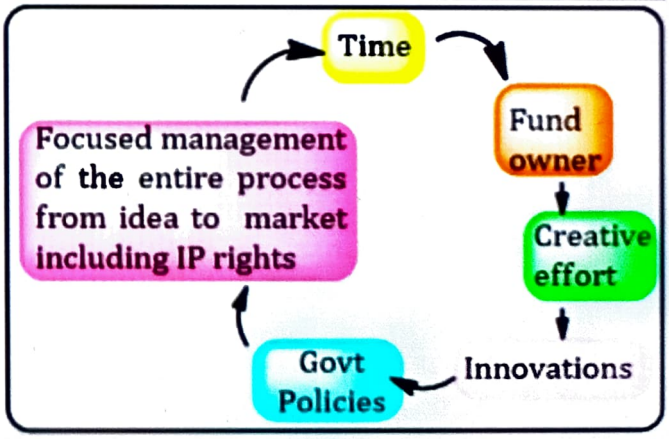
- **The process of turning an innovation or creative into a financially viable product, service, or method is known as commercialization**
- Before the study results can be brought to market, additional R&D, product development, clinical studies, or the development of strategies to boost manufacturing may be required.



❖ COMMERCIALIZATION-PRACTICAL ASPECTS:

S.NO	AMONG THE MOST IMPORTANT ASPECTS OF COMMERCIALIZATION ARE-
1.	Commercialization involves testing many ideas and selecting the products that can be safer, more effective, and more efficacious than the existing product.
2.	Commercialization is a step by step process. Therefore, set goals and milestones for every stage.
3.	It is important to involve key stakeholders, including customers, early in the process, including customers.

- By improving the technology transfer and commercialization contextual conditions, countries can **increase innovation** in the economy and thereby **raise productivity, create better job opportunities,** and **address societal challenges.**



- Not surprisingly, governments have been actively searching for new ways to **improve knowledge transfer from PROs to industry.**

TT AGENCIES IN INDIA –APCTD, NRDC, TIFAC, BCIL, TBSE/ SIDBI

❖ ASIAN AND PACIFIC CENTRE FOR TRANSFEER OF TECHNOLOGY (APCTT)

- It is a United Nations Regional Institution under the Economic and 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 development projects funded by international donors aimed at strengthening the environment for technology transfer among SMEs.
- The objective of APCTT is to strengthen the technology transfer capabilities in the region and to facilitate import/export of environmentally sound technologies to/from the member countries.

❖ NATIONAL RESEARCH DEVELOPMENT CORPORATION (NRDC)

- It was established in 1953 by the Government of India, with the primary objective to **promote, develop and commercialize the technologies / know-how / inventions / patents / processes emanating from various national R&D institutions / Universities** and is presently working under the administrative control of the Dept. of Scientific & Industrial Research, Ministry of Science & Technology.
- It is recognized as a large repository of wide range of technologies spread over almost all areas of industries, viz. Agriculture and Agro-processing, Chemicals including Pesticides, Drugs and Pharmaceuticals, Bio Technology, Metallurgy, Electronics and Instrumentation, Building Materials, Mechanical, Electrical and Electronics etc.

❖ TECHNOLOGY INFORMATION, FORECASTING AND ASSESSMENT COUNCIL (TIFAC)

- TIFAC is an **autonomous organization set up in 1988 under the Department of Science & Technology** to look ahead in **technology domain, assess the technology trajectories, and support innovation by networked actions in selected areas of national importance**
- TIFAC embarked upon the major task of formulating a Technology Vision for the country in various emerging technology areas.
- Under the **leadership of Dr. APJ Abdul Kalam,** Technology Vision 2020 exercise led to set of 17 documents, including sixteen technology areas and one on services.
- While inaugurating the 103rd Indian Science Congress in Mysuru, Hon'ble Prime Minister of India Shri Narendra Modi released the **Technology Vision 2035 prepared by TIFAC.**
- This is being followed by release of Technology Roadmaps in 12 thematic areas of national priorities and importance Education, Medical Science & Health Care, Food and Agriculture, Water, Energy, Environment, Habitat, Transportation, Infrastructure, Manufacturing, Materials and Information & Communication Technologies (ICT).

❖ BIOTECH CONSORTIUM INDIA LIMITED (BCIL)

- Biotech Consortium India Limited (BCIL), New Delhi was incorporated as **public limited company in 1990 under The Companies Act, 1956.**
- The consortium is promoted by the Department of Biotechnology, Government of India and financed by the All India Financial Institutions and some corporate sectors.

- BCIL's Major functions include the **development and transfer of technology for the commercialization of biotechnology products, project consultancy, biosafety awareness and human resource development**

❖ TECHNOLOGY BUREAU FOR SMALL ENTERPRISES (TBSE)/ SMALL INDUSTRIES DEVELOPMENT BANK OF INDIA (SIDBI).

- 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 and Pacific Centre for Transfer of Technology (APCTT) and Small Industries Development Bank of India (SIDBI) in 1995.**
- TBSE also receives partial funding from the Office of DC (SSI), Government of India.
- Features of TBSE Offering a **professionally managed system for the reasons of technology and collaboration exploration** helping in the building up of confidence between potential partner.
- It providing an opportunity to global technology market through the process of **networking**. Taking up project appraisal and the preparation of a business plan.
- The new technologies for the reason of transfer are sourced from countries namely China, Philippines, South Korea, Australia, Germany, as well as the U.S.

TT RELATED DOCUMENTATION - CONFIDENTIALITY AGREEMENT, LICENSING, MoUs, LEGAL ISSUES.

❖ CONFIDENTIALITY AGREEMENT

- It is also called as **non-disclosure agreement (NDA).** It is used to protect the **proprietary nature of the technology** and retain the **confidentiality** of a technology or invention.
- The **drafting of the appropriate clauses** can be essential for the maintenance of the value of the technology.
- The need of this agreement is due to the **increase in competition** and the **new technologies** can be exploited.
- Thus, it is necessary to obtain protection to the continuous innovation process through confidentiality agreements.

❖ LICENSING

- The legal core of the transfer of technology is constituted by a **licensing agreement.**
- By signing this agreement the owner of a technology, the licenser, gives the **right to another company**, the licensee, to make **use of this technology.**
- A license does not alter the **property rights** of the owner: he remains the only proprietor of the technology.
- The license agreement is generally referred to the licensing of **intellectual property rights** such as; patents, trademarks, copyrights, etc. This agreement has a role on maintaining the confidentiality and secrecy aspects of the contract.

❖ MoUs

- MoU stands for **Memorandum of Understanding**
- A Memorandum of Understanding is an agreement between two or more **parties outlined in a formal document.**
- It is not legally binding but signals the willingness of the parties to **move forward with a contract.**
- MOUs communicate the mutually accepted expectations of all of the parties involved in a **negotiation.**
- The MOU is most often found in **international relations.**

❖ LEGAL ISSUES

The following types legal issues are generally observed in technology transfer:

- ✓ **Legal contractual agreements**
- ✓ **Tax implications**
- ✓ **Legal issues in intellectual property transaction**
- ✓ **Problems associated with IPR litigation**
- ✓ **Legislations covering IPRs in India**