TECHNOLOGY DEVELOPMENT AND TRANSFER

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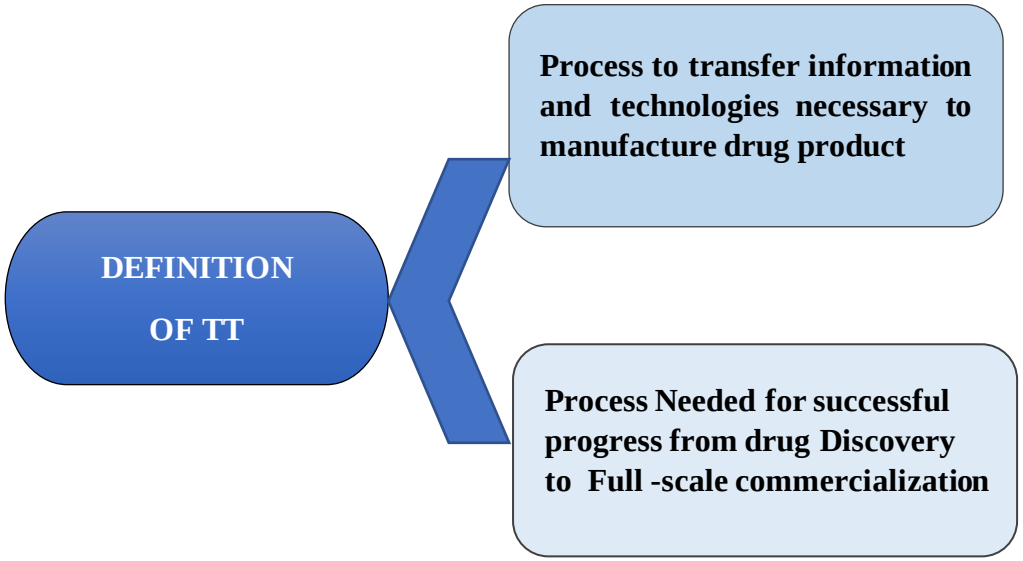


❖ OBJECTIVE

- To provide clear procedure for Technology Transfer process

❖ IMPORTANCE

- To elucidate necessary information from R & D to actual manufacturing process
- Applicable to relate TT through R & D and production i.e Drug substance to Drug Product
- Relate to Post marketing changes in manufacturing places .

❖ TERMINOLOGY

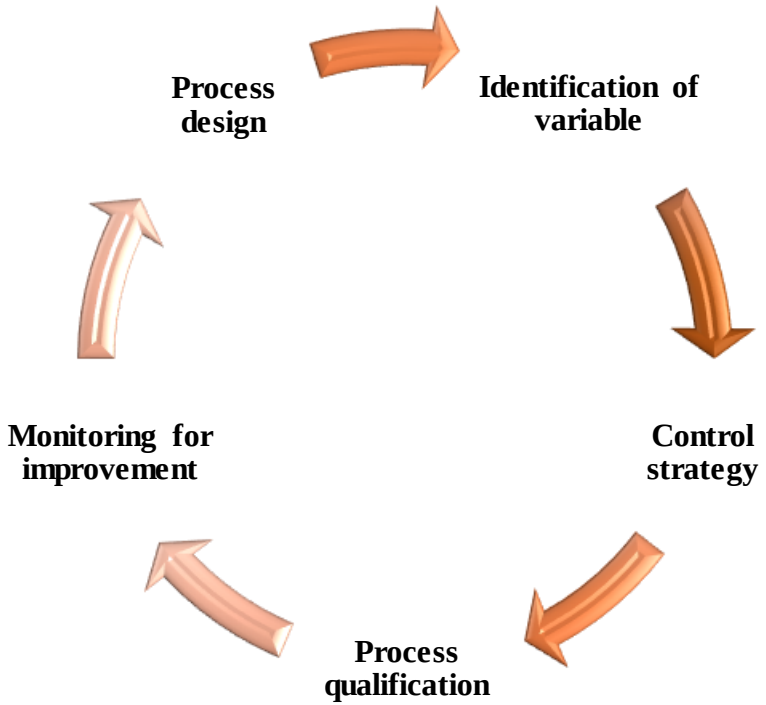
- Acceptance criteria
- Change Control (C/C)
- Critical control point (CCP)
- Drug Master File (DMF)
- Inter and Intra company transfer
- Quality Risk Management (QRM)
- Receiving Unit (RU)
- Sending Unit (SU)
- Transfer of Technology (TOT)
- Bracketing
- Corrective Action (C/A)
- Design Space
- Good Manufacturing Processes (GMP)
- In-Process Control
- Standard Operating Procedure (SOP)
- Quality Assurance and Quality Checking
- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Process Validation
- Validation Master Plan, Validation Report

❖ LIST INTENDED FOR TT PROTOCOL

1. Objective
2. Scope
3. Key Personnel & their Responsibilities
4. Parallel comparison of material equipment and method
5. Transfer stages with documented evidence
6. Identification of critical control point
7. Experimental design & acceptance criteria for analytical method
8. Information on trial and qualification batches and process validation
9. Assessment of end Product
10. Information about retention sample of API, Intermediate & Finished product
11. Conclusion, including signed off approval by Project Manager

❖ PROCESS VALIDATION

Documented act provide any procedure, process, equipment, material, activity or system actually leads to expected results.



Quality Risk Management

(QRM)

❖ DEFINITION

QRM is a systemic process for the identification assessment and control of the risk to quality of pharmaceutical product across product life cycle.

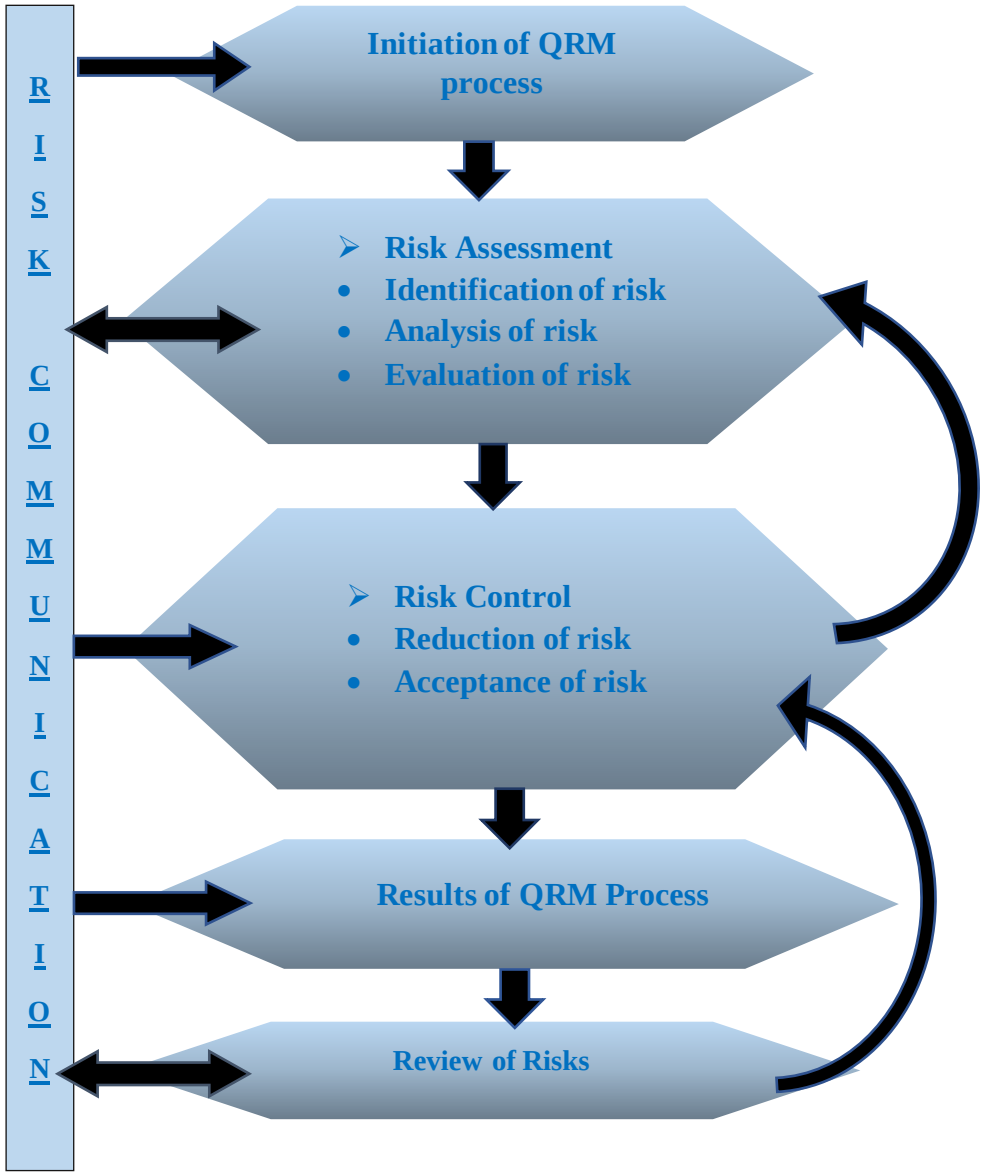
❖ SCOPE

The guidelines provide example of tools of quality risk management that can be applied to different aspect of pharmaceutical quality. The aspects include development, manufacturing, distribution, inspection and submission/ review process throughout the life cycle of drug substance, drug product biological and biotechnical product.

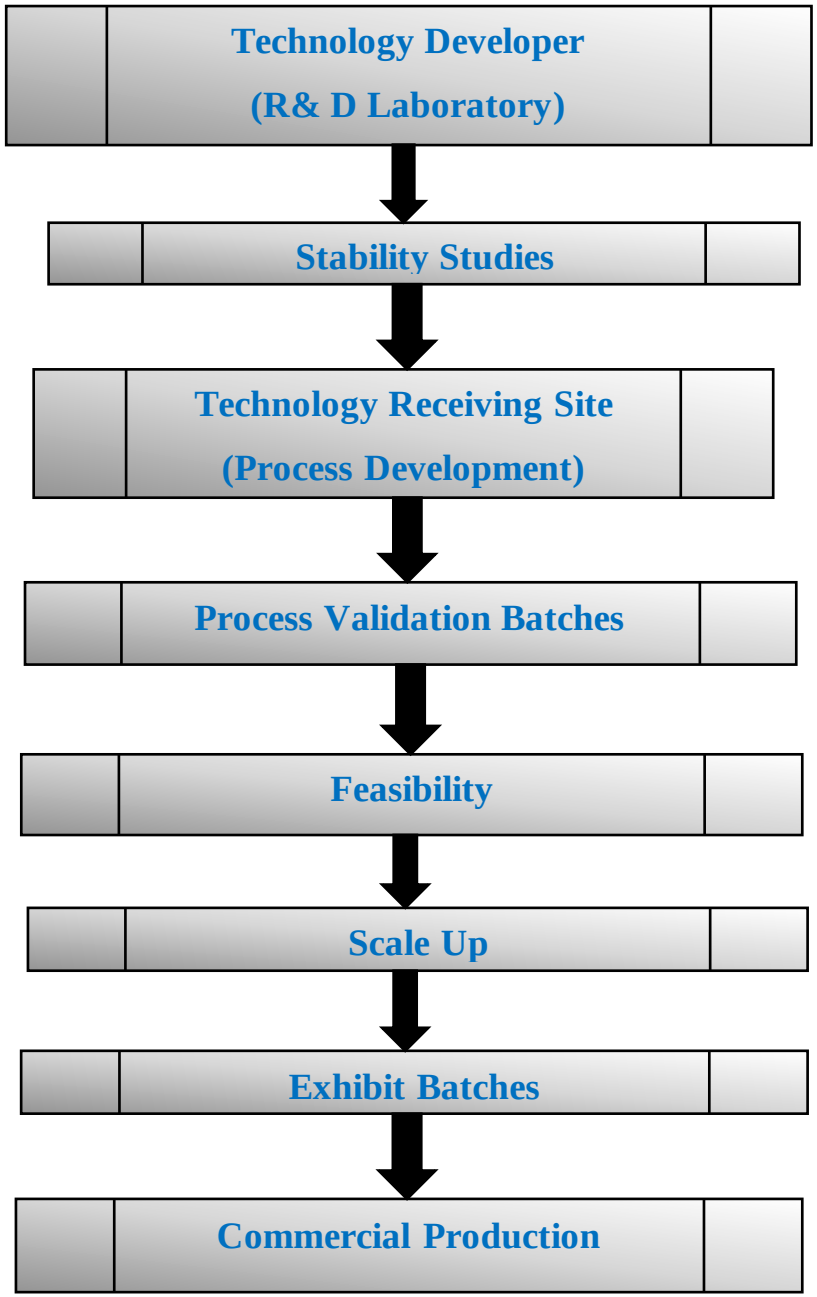
❖ PRINCIPLE

- Evaluation based on scientific knowledge and utility for patient protection.
- Level of effort, formality and documentation of QRM process should be commensurate with level of risk.

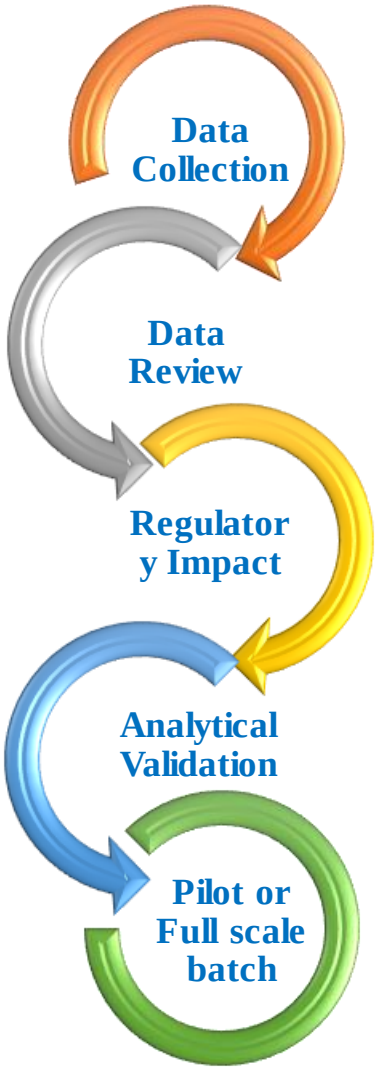
❖ PROCESS OF QRM



❖ TRANSFER FROM R & D TO PRODUCTION



❖ ST AGES IN TECHNOLOGY TRANSFER PROCESS



❖ GRANULARITY OF TT PROCESS

API:

Sending unit >> Drug Master File >> Receiving Unit

a) Manufacturer
b) Synthetic process
c) Dissolution rate
d) Handling requirements
e) Stability
f) pKa

Excipients:

Sending Unit >> Drug Master File >> Receiving Unit

a) Functionality
b) Manufacturer
c) Specifications
d) Regulatory Consideration
e) Special Consideration

Finished Product:

Sending Unit >>Information >> Receiving Unit

a) Definitive Form
b) Solubility
c) pKa
d) Ionic strength
e) MP, pH range
f) Moisture content
g) Adhesion Design

Packaging:

Sending Unit >>Information >> Receiving Unit

a) Specifications
b) Design
c) Processing
d) Labelling
e) QC testing
f) Art work

❖ DOCUMENTATION

1. Project Definition
2. Quality Agreement, Facility Agreement
3. Health & Safety Assessment
4. Skill Set Analysis & Training
5. Analytical Method Transfer
6. Evaluation, Equipment selection
7. Transfer
8. Process Transfer
9. Cleaning
10. Transfer of Technology Protocol

❖ INFORMATION

PREMISES:
Construction Layout
Ventilation,
Air Conditioning,
Temperature
Safety Issues

EQUIPMENTS:
List of Equipments
Model,
Standard Operating Procedure,
Good Manufacturing Practices,
Qualification Status

QUALIFICATION & VALIDATION:
Materials,
System ,
Procedure,
Methods of Transfer

QUALITY CONTROL :
Acceptance Criteria,Validation Protocol, Validation Report,
QC Testing Results,
Approved SOP's

ANALYTICAL METHOD TRANSFER :
Analytical Method Transfer
Protocol

❖ TT AGENCIES IN INDIA

APCTT
- Asian & Pacific Center for Transfer of Technology
- Established - **1977**
- To strengthen TT capability in region

NRDC
- National Research Development Corporation
- Established - **1953**
- Patent the product for Commercial Exploitation

TIFAC
- Technology Information , For casting, Assessment Council
- Established - **1988**
- Support innovation by networked actions in selected areas

BCIL
- Biotech Consortium India Limited
- Established - **1990**
- Development & TT for the commercialisation of Biotech product

TBSE
- Technology Bureau For Small Enterprises
- Established - **1995**
- Project appraisal & preparation of business plan

SIDBI
- Small Industries Development Bank of India
- Established - **1990**
- Facilitate & stregthen credit flow to Micro, Small & Medium Enterprises

❖ APPROVED REGULATORY BODIES AND AGENCIES

- Central Drug Standards & Controls Organisation (CDSCO)
- Drug Controller General of India (DCGI)
- Food & Drug Administration (FDA)
- Therapeutic Goods Administration (TGA)
- Medicines & Healthcare Products Regulatory Agency (MHRA)

❖ TT RELATED DOCUMENTATION

Confidentiality Agreement:

- Brief Description of Technology
- Specification of Technology
- Relevant Application

Licensing:

- Limited Rights
- Give Right to Another Company
- Doesn't alter property Rights

Memorandum of Understanding:

- Roles & Responsibilities of parties
- Licensing Income Sharing Details
- Intellectual Property Managements

Legal Issues :

- Tax Implications
- Legal Contractual Agreements
- Legislations covering IPRs in India

❖ REFERENCES

1. www.iptsalipur.com
2. www.kppub.com
3. www.sidbi.com
4. https://services.india.gov.in

- DEPARTMENT : PHARMACEUTICS
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