

Assessing Technology Transfer Stages and Expectations



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Technology Transfer: *Definition*

❖ Annex 7 World Health Organization

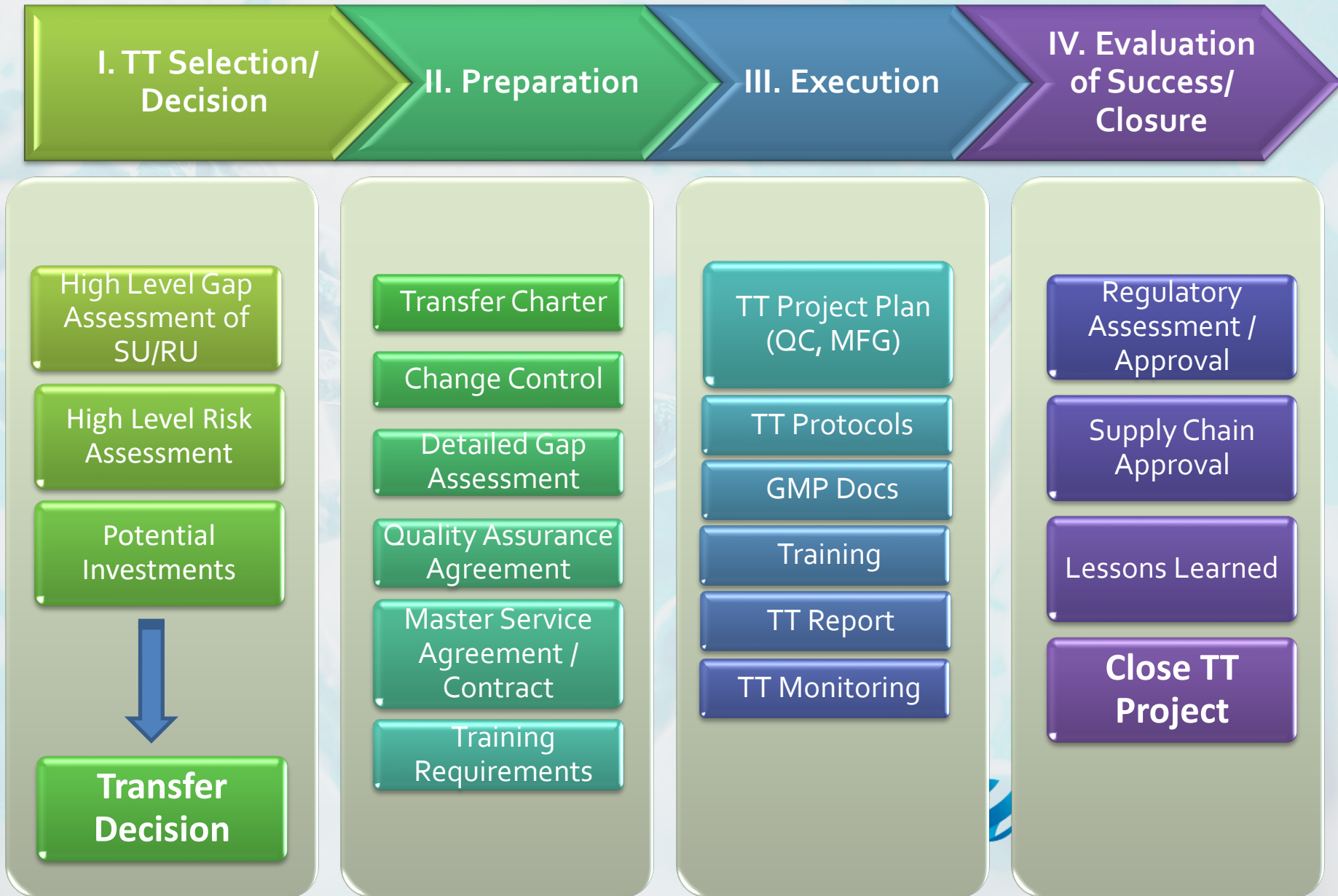
- *Transfer of technology is defined as “a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites”.*
- *It is a systematic procedure that is followed in order to pass the documented knowledge and experience gained during development and or commercialization to an appropriate, responsible and authorized party.*
- *Technology transfer embodies both the transfer of documentation and the demonstrated ability of the receiving unit (RU) to effectively perform the critical elements of the transferred technology, to the satisfaction of all parties and any applicable regulatory bodies.*

Technology Transfer: *Objective*

❖ ICH Q10

- *"The goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realization. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach, and ongoing continual improvement."*

Technology Transfer: *Phases*



Technology Transfer Phase I

TT Selection/ Decision

High Level Gap
Assessment of SU/RU

High Level Risk
Assessment

Potential
Investments



Transfer Decision

- ☐ High Level Gap Analysis of SU/RU or Process/Product Owner
 - Manufacturing Process
 - Analytical methods
 - Materials/ Supplier
 - Equipment
 - Environmental Health and Safety
 - Packaging (if applicable)
 - Supply Chain
 - Legal / Regulatory Situation
- ☐ High Level Risk Assessment
 - Equipment (Long Lead Time) and Qualification
 - Personnel Training
 - Materials and Supplier Qualification
 - Construction
- ☐ Potential Investments
 - Equipment Purchase
 - Construction or retrofit of a facility or equipment
- ☐ Evaluation → Decision

Technology Transfer Phase II

Preparation

Transfer Charter

Change Control

Detailed Gap Assessment

Quality Assurance Agreement

Master Service Agreement / Contract

Training Requirements

- ☐ Transfer Charter
 - Project Name
 - Objective
 - Scope – Process / Method Development, Scale-Up, Engineering Run, Aseptic Process Simulation Run(s), Process Performance Qualification Run(s), Characterization Study, Method Validation, Comparability Study
 - Project Team
 - Deliverables
 - Technical Risks
 - Resources / Supply Chain
 - Timeline and Milestones
 - Stage Gates
- ☐ Change Control (Parent and Child)
- ☐ Detailed Gap Assessment (Continued)
 - CPP/CQA, QTPP, In-Process Controls
 - Qualification Status (Facilities, Utilities, Equipment, Analytical Method)
 - GMP and Quality System Documents (MBR, SOP, WI, Analytical Test Specs, Material Specs)
- ☐ Quality Assurance Agreement – GMP Documents Review/Approval Process, Product Release Requirements
- ☐ Master Service Agreement / Contract
- ☐ Training Evaluation and Requirements
 - Process
 - Analytical Methods

Technology Transfer Phase III

Execution

TT Project Plan
(QC, MFG)

TT Protocols

GMP Docs

Training

TT Report

TT Monitoring

- ❑ TT Master Plan and Project Plan(s)
 - Strategy and Objective
 - Product Master Data/Specs – Acceptance Criteria
 - Product Characteristics
 - Ingredient Incompatibility
 - Stability Information
 - Environmental Conditions
 - Safety Requirements
 - Sampling Information
 - Documentation
 - APS Runs
 - Engineering Runs
 - PPQ - No. of batches
 - Stage Gates and Criteria
- ❑ TT Protocols (Process - USP/DSP and Analytical Methods – In-Process and Release)
- ❑ GMP Documentation (SOP, WI, MBR, Test Specs, Analytical Methods)
- ❑ Training (Process, QC Methods, Documents, Impact to CPP/CQA)
- ❑ TT Report(s)
- ❑ TT Monitoring (Scope/Acceptance Criteria Changes and TT Status)

Technology Transfer Phase IV

Evaluation of Success/ Closure

Regulatory
Assessment /
Approval

Supply Chain
Approval

Lessons Learned

Close TT Project

- ☐ Regulatory Assessment and Approval
 - Review of TT Report(s) against TT Master or Project Plan(s)
- ☐ Supply Chain
 - Process Approval
- ☐ Lessons Learned
 - Apply to the next TT Phase or Technology Transfer Project
- ☐ Close TT Project Report

Project Team

Sending Unit (SU)

Receiving Unit (RU)

**Product / Process
Owner**

Manufacturing

Process Development

Quality Control / Analytical

Quality Assurance

Validation

Engineering

Regulatory

Mfg. Science & Technology

Supply Chain / Purchasing

Project Manager /
Account Manager

Legal

Project Controls

Project Sponsor(s) /
Steering Committee

- ☐ Identify the Project Team Member(s)
- ☐ Ensure Escalation Levels are identified
- ☐ Identify Project Sponsor(s) / Steering Committee
- ☐ Establish clear Roles and Responsibilities / RACI

Technology Transfer Tools Enabling Collaboration



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TT Tools Enabling Collaboration

1) Quick TT Reference Guide

- Project Team
- Project Folder Structure and Location
- Project Schedule Location
- Gap Assessment and Tracker Tools

Main Folders	
Name	
000 Quick TT Reference Guide	
00 Transfer Charter	
01 Meeting Minutes	
02 Schedule and Milestones	
03 Gap Assessments	
04 Risk Assessment	
05 Tech Transfer Plan and Report	
06 Process Flow Diagram	
07 MFG Documents	
08 QC Documents	
09 QA Documents	
10 Regulatory Documents	
11 Supply Chain Documents	
12 Change Control	
13 Project and Account Mgt	
14 Lessons Learned	

Sub-Folders	
Name	
07.01 SOPs	
07.02 Process Development	
07.03 Scale-Up	
07.04 APS	
07.05 Engineering Run	
07.06 PPQ Run	
07.07 Process Description	

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2) Project Monitoring and Reporting

- Project Schedule: MS Project or Smartsheets
- Project Dashboards or 4-Box

Task Name	Duration	Start	Finish	Predecessor	Responsible	Reviewer / Approver	% Complete	Status
Transfer Selection / Decision	156d	08/30/21	04/04/22				10%	In Progress
Project Name or Product Name	1d	08/30/21	08/30/21				100%	Complete
Transfer Idea - Project Charter	55d	08/31/21	11/15/21				29%	In Progress
High Level Gap Analysis between SU/RU	16d	09/14/21	10/05/21				7%	Not Started
High Level Risk Assessment	10d	10/06/21	10/19/21				0%	Not Started
Transfer Project Decision	100d	11/16/21	04/04/22				0%	Not Started
Preparation	168d	11/16/21	07/07/22				2%	Not Started
Change Control (CC) at RU	50d	04/05/22	06/13/22				0%	Not Started
Technology Transfer Master Plan (TTMP)	45d	11/23/21	01/24/22				13%	Not Started
Detailed Gap Assessment	10d	06/24/22	07/07/22				0%	Not Started
Analytical Method Development / Qualification	15d							
Process Development and Scale-Up								

Execution
GMP and Quality System Document Availability
Tech Transfer Plan - (Analytical Method and MFG)
Qualification Execution
Process TT Runs
TT Monitoring (Changes and Status)
TT Master Plan Report
Finalize Product Specifications
Evaluation of Success / Closure
Regulatory Assessment / Approval
Supply Chain
Lessons Learned
Close TT Project

Project Lead	
Czarina Santos	
Project Start	Project Closure
Date	Date
07/01/21	07/19/22
Project Phase % Completion	
Initiation	60%
Execution	6%
Closure	0%
Useful Links	
21 COM12 Bulk Tank Project LN2 LO	

Description
Trackwise ID: 705504
Qualification of newly installed bulk tanks (LN2, LO2 and LCO2) and a Nitrogen gas distribution system
Bulk Tanks and Nitrogen gas distribution system are newly installed equipment for Building A

Accomplishments / Highlights
RA (USHA-10974) for Nitrogen system has been approved.
VPP (USHA - 11224) review cycle completed.
SLIA for all three (30 bulk tanks are routing for signatures.

Status
Final tie in for bulk tanks is not installed yet
Qualification Documents Development Status - refer to Summary Report
Test Logistics (for QC Release) not in place yet. Material release is a pre-requisite for qualification
URS is in approval process. URS finalization necessary for generation of Qualification Protocol
Issues / Challenges
Need clarity from QC of what the material release procedure will be.

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3) Technology Transfer Templates

- Transfer Charter
- TT Master Plan or Project Plans (QC/MFG)
- Gap Assessments and Tracker Tools
- Risk Assessments
- Lessons Learned
- Meeting Minutes
- SOPs / Work Instructions / Batch Records



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Thank you for joining us!