Management of product transfer projects

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Content

- 1. Technology Transfer Project Structure
- 2. Risk management
- 2. Best practices
- 3. Workshop "Create transfer project plan"









PROJECT STRUCTURE

TECHNOLOGY TRANSFER

Technology Transfer Process: Phases



A planned systematic sequence of activities that is followed in order to transfer manufacturing of a pharmaceutical product from one unit to another





Phase 1: Transfer Initiation- BC

Objective

Preparation of a TT business case to gain funding and approval for the project

- **Before beginning** this phase, you will need:
 - 1. Clear understanding of the idea and business need with assumptions
 - 2. Overview of the current situation and the proposed situation
- At the conclusion of this phase, you will have produced:
 - 1. Project initiation decision
 - 2. If approved, funding for the entire project

Key Activities

- 1. Create high-level process/ testing/ quality & regulatory requirement
- 2. Conduct high-level gap assessment
- 3. Gather cost estimates
- 4. Provide Business Case for Decision





Phase 2: Transfer Planning

Objective

- The aim of this phase is to *evaluate the risks associated with the transfer,* establish a suitable risk control strategy and define the deliverables of the project.
- **Before beginning** this phase, you will need:
 - 1. Approved business case
- At the conclusion of this phase, you will have produced:
 - 1. Approved TT Plan
 - 2. Agreement on deviations from approved business case
 - 3. Passed Gate Review (if necessary)

Key Activities

- 1. Form project team and structure
- 2. Gather current product and process data
- 3. Conduct risk assessments and define risk control strategies
- 4. Define the test method transfer, process transfer and validation approach
- 5. Define Regulatory Strategy
- 6. Define required activities for launch and commercial production
- 7. Validate business case cost and time assumptions
- 8. Finalize Transfer Plan and deliverables
- 9. Organize Gate Review (if necessary)





Project Gantt Chart (high level), example

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Project Gantt Chart (high level), TMT example

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		42	Completion of TMT for Excipients	s (site ready for testing)		16-FEB-16	15-FEB-16		11-FEB-16-15-FEB-16	
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		- 46	Obtain QA approval to test comm	mercial product		21-JAN-16	30-JAN-16		11-JAN-16.	
		47	Execute TMT for Drug Product			31-JAN-16	20-FEB-16		21-JAN-15.4, 30-JAN-16	
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Internal resource planning, example

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External resource planning, example

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Project team (work stream)



Ad-hoc: Marketing, Market access, Finance.





Project Transfer Plan: typical information

Project overview

- Scope Executive Summary
- Supply Chain Flows
- High level Transfer Strategy

- Project Team

- Team members RACI Matrix
- Communication and meeting frequency
- Issue elevation process and gate reviews

Technology transfer technical elements and proposed change management strategies:

- Composition unit formula Raw materials Function of components and source Change strategy
- Batch sizes Manufacturing formulas Sending Unit -Receiving - Changes strategy
- Manufacturing Process and Manufacturing Instructions, including In Process Controls (from CTD) - Sending Unit -Receiving Unit - Changes strategy
- Packaging requirements Packaging formula Packaging materials- specifications
- Product characteristics necessary for cleaning validation Cleaning efficiency assessment / validation approach

- Technology transfer technical elements and proposed change management strategies cont'd:
 - EHS considerations Material safety data sheet EHS analysis and mitigation approach
 - Analytical Methods and controls
 - Specifications
 - Test Methods
 - Test Methods transfer strategy, including risks and mitigation strategy
 - Manufacturing Risk Assessment mitigation strategy
- Process validation (including supportive process development activities, if necessary) and Stability assessment strategy, with reference to quality and regulatory needs
- Regulatory Strategy
 - Source documents reference and documentation update strategy
- Appendix 1: EHS API, Drug Product & Packaging Transfer Checklist
- Appendix 2: High level Transfer Schedule





Phase 3: Transfer Execution

Transfer Execution

Objective

- To execute the deliverables as defined in the TT plan and gain market approval
- **Before beginning** this phase, you will need:
 - 1. Approved TT plan
 - 2. Passed Gate Review (if necessary)
 - 3. Agreement on deviations from approved business case
- At the conclusion of this phase, you will have produced:
 - 1. Complete hand-over of robust process and/ or analytical method to receiving unit
 - 2. Market approval
 - 3. FLQR approval
 - 4. Launch readiness
 - 5. Passed Gate Review (if necessary)

Key Activities

- 1. Ensure QA audit is in place
- 2. Complete receiving unit site readiness and finalize receiving site quality documentation
- 3. Complete Test Method Transfer
- 4. Perform engineering/ registration/ validation/ batches/ EHS monitoring (as required)
- 5. Initiate stability and hold time studies
- 6. Prepare dossier for regulatory submission
- 7. Submit dossier and respond to deficiency questions
- 8. Complete FLQR approval
- 9. Define post-validation monitoring plan (if applicable)
- 10. Prepare the site for commercial production (launch readiness)
- 11. Organize Gate Review (if necessary)





Phase 4: Transfer Closure

Objective

- To complete the TT process
- To capture lessons learned in order to facilitate improvements
- To complete hand-over to commercial production phase
- Before beginning this phase, you will need:
 - 1. Completed the hand-over of robust process and/ or analytical method to receiving unit
 - 2. Gained Market approval
 - 3. Gained FLQR approval
 - 4. Completed launch readiness
 - 5. Passed Gate Review (if necessary)
- At the conclusion of this phase, you will have :
 - 1. Disbanded TT project team
 - 2. Increased team member TT skills and abilities
 - 3. Completed lessons learned
 - 4. Delivered the value to the business as defined in the business case
 - 5. Confirmed that all non-quality documents are captured in approved repository

Key Activities

- Perform lessons learned session with project TT team (and as appropriate with sending and receiving units)
- 2. Conduct closure meeting to
 - Ensure that business case is achieved
 - Confirm that all required steps outlined in TT plan have been completed
 - Transfer ownership and documentation to appropriate function
- 3. Implement post-validation monitoring (if needed)
- 4. Celebrate successes





TECHNOLOGY TRANSFER

RISK MANAGEMENT





FMEA (ich q9)

- The Failure Mode Effect Analysis responds to the need of anticipating and possibly moderating/avoiding unexpected/undesired/critical situations a process/product/system may incur.
- Simply put, the **basic FMEA** is a structured approach to:
 - Identifying the ways in which a product/process/system can fail
 - estimating risk associated with the failure
 - identifying and prioritizing the actions that should be taken to reduce risk





Risk evaluation

- Risk related to Failure Mode is evaluated:
 - for each Failure Mode
 - for the overall system/process/product in scope
- Risk level may be:
 - accepted (nothing is done)
 - eliminated or reduced to acceptable level through prevention/moderation actions
- Risk acceptance criteria are set according to regulatory constraints/and/or business objectives,







Risk Priority Number calculation

The **Risk Priority Number (**RPN) is an index used to **evaluate failure risk** and identify critical areas eligible/priority for corrective/preventive action







Probability

- Estimates the probability that the entire sequence Cause/Failure/Effect may occur.
- Probability estimation may involve:
 - quantitative evaluation of historic occurrences
 - qualitative evaluation according to subjective experience, expertise

Probability that the Effect of Failure Mode occurs



Detectability D

- Estimates the likelihood (or in negative terms the difficulty) of identifying and preventing/interrupting the sequence cause-failure-effect
- Failure impact may extend in time (impact continues until failure is resolved) or may spread across process/system/product (failure triggers other failures). Effect of failure may be strongly dependent on mechanism/timing of failure detection.
- A failure may have more than one/many Causes.







Severity S

- Estimates the impact/damage caused by the Failure
- Depending on the scope/domain of analysis:
 - may involve different actors (customer, user, process owner, operator)
 - may and multiple a wide range of impacts/damages, from annoyance, to efficiency reduction (waste) to personal death/injury to operator/customer/owner
- A Failure may have more than one/many effects;







FMEA deliverable

Process/Product Failure Modes and Effects Analysis Form (FMEA) Processor Proparodby: Page_ ___ of ____ Product Nam Responsible: FMEA Data (Orig), (Rev) Process 0 O Potential Potential Potential Actions Actions D D s С Current Controls s С Step / Resp. Failure Mode Failure Effects Causes Е **Becommended** Taken E T Е С Е С Input т ¥ U U In what ways does What is the impact What causes the Key What are the existing What are the What are the What is the Е R E C R Е R Ε R process the Key Input go on the Key Output Input to go wrong? controls and P actions for completed С Р R R R R step and wrong? Variables procedures (inspection reducing the actions taken т N Т N Е Е I н and test) that prevent occurrence of the Input under (Customer with the т т Ν Ν investiga-Requirements)? either the cause or the cause, or recalculated O O С Y С Y tion? Failure Mode? BPN? improving N N Е Е detection? 0 0 0 0 0 0 0 0 0 ystem/process/prod System/process/pr **RISK EVALUATION** Assessed current **RISK EVALUATION** and probability P Mode effects and **Potential Failure Potential Failure** oduct Elements detectability D Mode causes uct Elements controls and and priority and priority serverity S analyzed analyzed prevention/mitig ation action plan





TECHNOLOGY TRANSFER

BEST PRACTICIES





Tools/Template

Area	System	Template
Collaboration	Teamsite- SharePoint	
Planning	 TTP RACI ESH Planisware/ Ms Project 	<u>Tech Transfer Plan</u> <u>RACI matrix</u> <u>Ms Project Tech Transfer</u>
Gate reviews	• Gate 1, 2,3 ,4	Gate 1 review - Go/No go with transfer Gate 2 review - Go/No go to proceed with Validation PV1 Gate 3 review - Go/No go to continue validation PV2+3 Gate 4 review - Go/No go with submission
Risk assessment	 Risk/Gap assessment High level, FMEA 	Gap/Risk assessment high level FMEA
Agenda/Minutes	Agenda & Minutes	Agenda/Minutes Action list
Lessons learned	Lesson learned template	Lessons learned and handover





Thoughts to Consider

DO

- Maintain clear and open communication between all parties
- Gather the right information
- Review the history to help find issues
- Review the regulatory compliance status – any variations?
- Develop contingency plans
- Plan for risk
- Understand your variability and control it in your process
- Process aligned to the formulation
- Well defined and technically justified critical performance parameters

DON'T

- Make assumptions without question
- Change parameters without adequate support
- Take too many risks, and then only with a thought out plan







Вопросы?

academy@veropharm.ru



