Technical Transfer to CMO

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Technical Transfer

Technology Transfer (TT)

ICH Q10

- The goal of Technology Transfer activities is to transfer of product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realization.

***Collection of processes involved in a product's life cycle**, from its conception to its completion. This term is all-encompassing, and touches on every stage of design, development, manufacturing, packaging, shipping, and equipment maintenance.*

Technical Transfer Model

Internal & Internal

-Most straight forward

-Uniform organizational culture, seamless knowledge integration

-Integrated systems

- Tacit Knowledge
- Complacency

Internal & External

- Strategic partnership
- Advantage of the specialized skills, technology, and capacity of 3rd party experts
- Internal team to focus on core competencies (R&D, etc)

- Protecting proprietary information
- Alignment of quality standards and priorities

External & External

- Least straightforward
- Leverage diverse capabilities, efficient scaling,
- Market expansion

- Coordination complexity
- IP protection
- Consistent quality across entities

Why Technical Transfer?

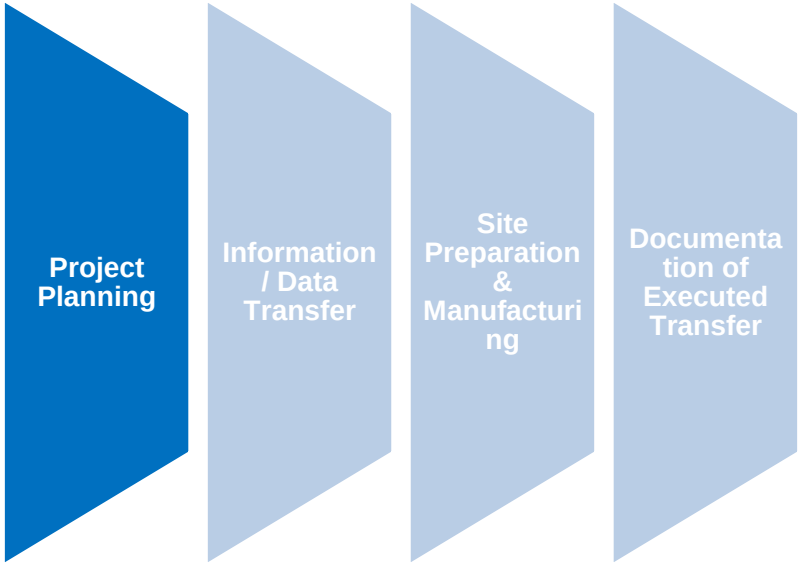
Importance

- Business continuity and scalability
- Securing market advantage through commercialization of new technologies
- Securing financial benefits compared to large-scale development cost
- Guaranteeing the rights and interests of intellectual property owners and contribution to the public

Technology Transfer Key Milestones

- Project Planning
- Information / Data Transfer
- Site Preparation & Manufacturing
- Documentation of Executed Transfer

Project Planning



Process Fit to Plant (PF2P)

- ✓ PF2P must be prospectively established and executed between the sending site and the receiving site to manage risk and assure the equipment capabilities and operating environment of the plant
- ✓ The process is implemented as intended at the receiving site, starting from the first batch with SMEs

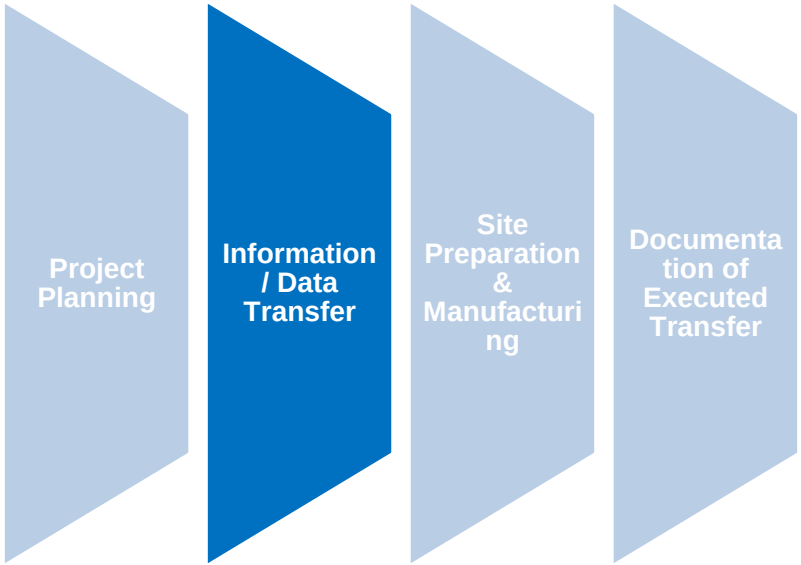
Technology Transfer Plan (TTP)

- ✓ A team is assembled for a given technology transfer (SMEs are critical)
- ✓ Alignment on objectives, deliverables, and success criteria (high level)
- ✓ Technical Assessment and Risk Management

Change Control

Validation Master Plan

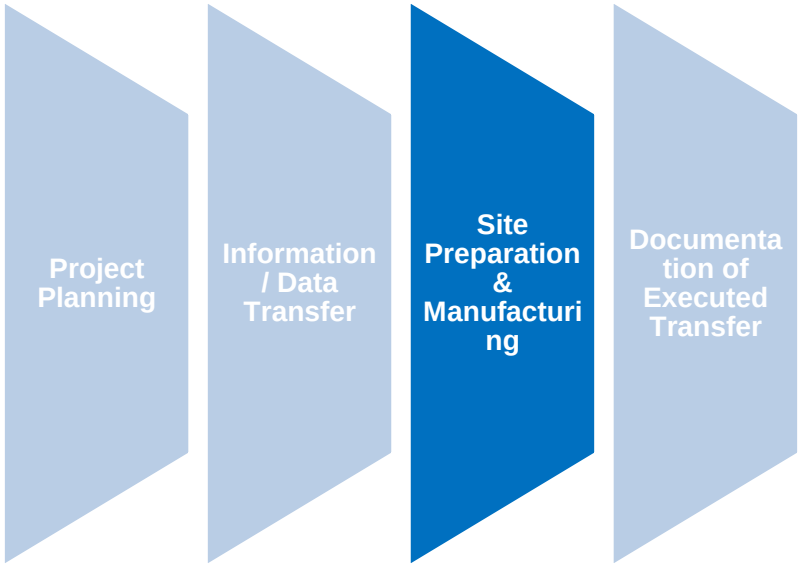
Knowledge Transfer



Product related detailed technical execution plan and justification

- ✓ Lab Assessment
- ✓ Method Transfer Protocol (Commercial)
- ✓ Specification
- ✓ Criticality Analysis
- ✓ Material Assessment (part of MQ)
- ✓ Detailed Process Flow Diagram (DPFD) – sampling plan included
- ✓ Protocols for Development, Characterization, Comparability and Stability
- ✓ Assessment for Cleaning Validation/Verification
- ✓ Validation Protocols (Commercial)

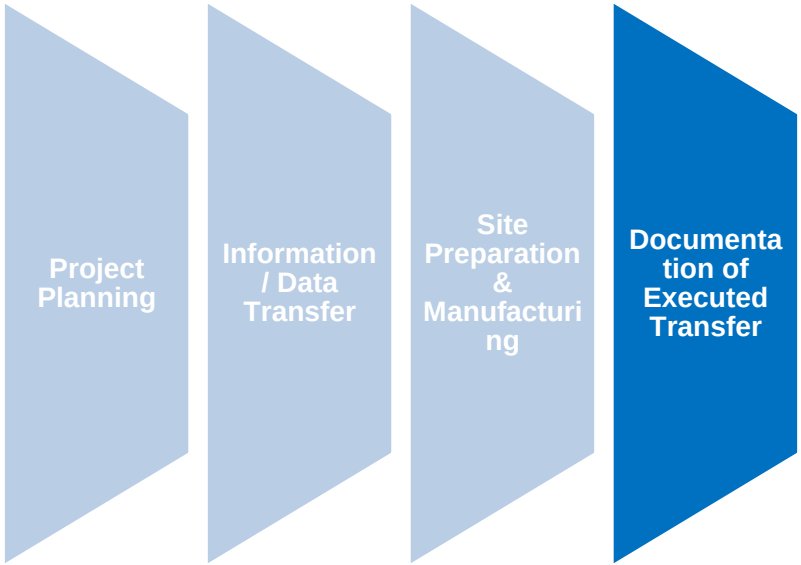
Site Prep. & Manufacturing



Site Specific Actions and Readiness

- ✓ Analytical Lab Qualification
- ✓ Production Readiness Check (Prerequisites)
- ✓ Master Batch Records (Commercial)
- ✓ Batch Record
- ✓ Prepare site system (LIMS, site WI/SOP, recipes, training, equipment change control, EHS assessment)
- ✓ Well-trained operators and analysts
- ✓ Equipment Qualification
- ✓ Manufacturing Qualification
- ✓ Cleaning, Sterilization and Testing Qualification

Documentation



Documentation of Executed Transfer

- ✓ Documented Analytical Transfer
- ✓ Certificates of Analysis and Compliance
- ✓ Executed Batch Records
- ✓ Cleaning report (verification report)
- ✓ All other executed protocols/ reports
- ✓ Executed validation/verification protocols/ reports
- ✓ Technology Transfer Report
- ✓ Batch report
- ✓ Etc

Take-away

- Avoiding the technical transfer pitfalls requires **a thorough and well-planned tech transfer process** that includes **detailed documentation, robust communication**, **comprehensive training, and careful alignment of processes and quality standards** between the original and new manufacturing sites.

Tips for Technical Transfers (To reduce cost, time, and risks)

Science & Dara Strategies Leveraging technology to accelerate transfers by	• Embedding **the use of Advanced analytics and Modeling into the process** • Integration of **Smart Tech Transfer** and related initiatives • Connecting with Integrated quality, Technology and Digital programs • Identifying opportunities to leverage and standardize tech-enabled execution and digital plat forms
Program Capabilities Establishing best practices to improve efficiency by	• Building the TO specific layer of TT Playbook • **Implementing a Central Project repository** • Deployment of a Process for cross-functional alignment and oversight in project execution • Building Training and Governance process
Partnership & Integration Implement One Tech Transfer process to increase agility by	• Defining on One TT process that encompasses all transfers across all platforms • Defining R&R for secondary transfer for New Products (prior to Transfer of ownership)

CMO Case Study

Main challenges/difficulties in TT for CMO

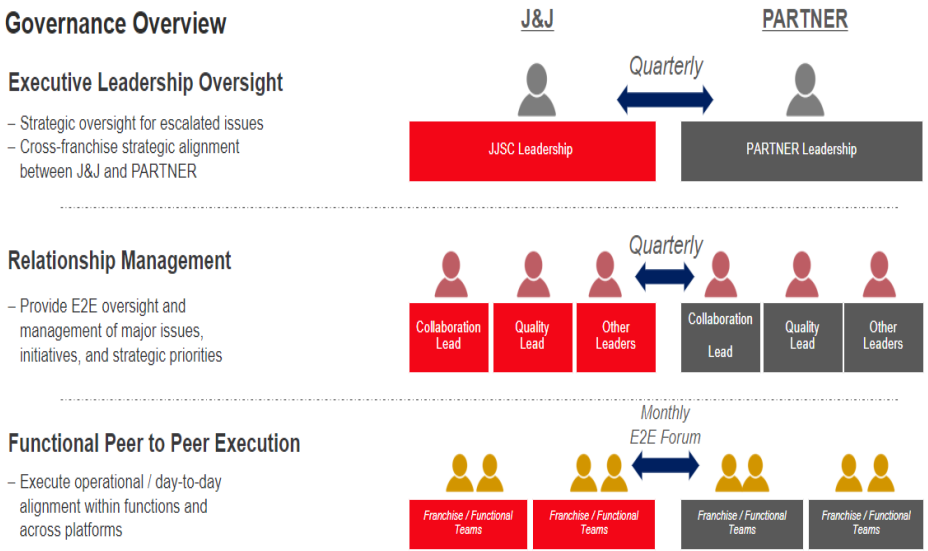
- Our process for TT has evolved over the years so that it is executed similarly across internal and external sites. A major difference that needs to be addressed when working with a CMO, is **R&Rs for defined TT deliverables and document authoring/approvals as CMO sites can be structured differently** versus our internal sites. Not a major problem, just something that needs to be acknowledged up front and defined so there are no surprises down the line.

- We see no difference between global regions (except time zone challenges!) and have successfully transferred across all regions globally.

Importance of Governance Alignment

The biggest risks for a tech. transfer is not technical complexity or knowledge management, but instead **organizational complexity** and **supplier management**

Define the Governance Hierarchy and Forums



Elements for Successful Technology Transfer

Right capabilities in the team to support the TT:

- Sufficient experience to help with evaluating PF2P (Process Fit to Plant) differences/risks and ensuring sufficient mitigations are put in place
- Technical capabilities to manage the transfer, interpret and challenge process data, mitigate process investigations should they arise
- People skills to lead and navigate a large, global, cross-functional team!

Common Reasons for TT Failure

Challenges in Oncology Product

- Time Constrains: Significant challenge in tech transfers and launches.
- Urgency vs. Evaluation: Rapid market entry limits thorough evaluation, extending timelines
- Deadline Pressures: Aggressive submission deadlines may impact product quality and PPQ
- *Risk Mitigation: Engineering runs attempted, but scheduling before validation is often difficult*

Common Reasons for TT Failure - Continued

Challenges in PPQ Optimization

- Optimization Drive: Desire to implement phase 3 learnings in PPQ
- Critical Decisions: Assess process impact – distinguish “must haves” from “nice to haves” in PPQ. Ensure rigorous assessment of changes affecting comparability
- Increased Scrutiny: PPQ are closely examined; minor trends must be explained
- Variability Challenges: Aggressive timelines can hinder understanding of process variability
- Personal Expertise and Training: New manufacturing team need comprehensive training programs focusing on process specifics and quality standards

What to Look @ CMO from a Quality Perspective

Similarity as an internal site:

Health Authority Inspection History
- Assess any major risks identified
- Review outstanding observations/resolutions

Internal Audit Preparedness
- Conduct audits to evaluate the quality systems
- Ensure readiness for new product introduction

Site Infrastructure Capability
- Confirm infrastructure can support required staff levels
- Verify sufficient training for employees to execute process effectively

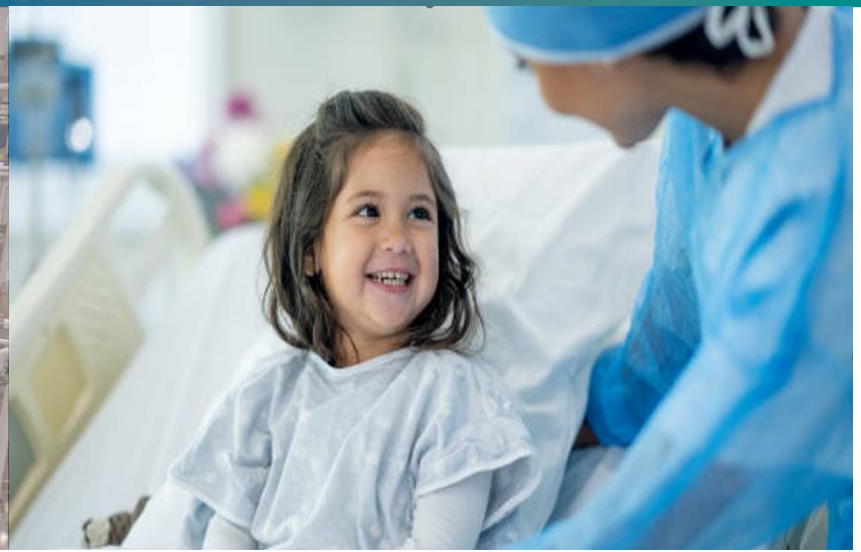
CMO Experience
- Evaluate the CMO's ability to manage and resolve quality investigations
- Emphasize the importance of robust and thorough investigation processes

Tech Transfer Agreement / Quality Agreement

Technical Transfer Agreement:
Ensures both parties have a clear understanding of the technical processes, responsibilities, and expectations. It outlines the specifics of the technology, processes, and knowledge being transferred.

Quality Agreement:
Details the quality standards and practices that need to be maintained. It aligns both parties on quality requirements, ensuring the product meets regulatory and company standards.

Overall, these agreements are foundational to ensuring a successful and compliant transfer of technology and production capabilities, helping to protect both the transferring company's interests and the quality of the final product.



Q & A