



Tech Transfert et ses opportunités
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Key Learnings for a Successful Tech Transfer and Beyond

JP Fonta



Objectives

Share learnings, reflexion and experience over many TT and aftermaths

- Learning during and after
- Pitfalls

What happened during and also after up to filing and under Operations

Tech Transfer, a Major Activity in Today Industry for Development and Securing Supply

For Development

- Capacity for Development of several products simultaneously
- Flexible Manufacturing during Development
- Reach market quickly
- Access new technology with capacity

From Development to Operations

- Capacity for Manufacturing and Supply

For Operations

- Back up to secure Supply
- Maximize Capacity available
- Cost efficiency
- Organization change



Unfortunately at Time May Fail to Recognize TT activities internally and externaly

Confronted with many shades/types of TT

Can be purely internal or external or mix

At time fail to recognize activities which are TT and requiring proper management as TT

Should ask the question whenever
changing environment for
the process



TT must be Recognized as a Strategic Decision

Engaging your Company for the Future

Strategic Dimension

- Secure continuity of Development and Operations
- Built as a bridge from Past to Future
- Significant financial and business impact



Need to be:

- Designed and organized with future in mind
 - Align with Business Objectives
 - Secure Filing, Inspection and Supply
- Considered as an extension of your Facility/Company under your responsibility
- Long term investment and not just a one off transfer away

Often Overlook the Tough Part and Future Implications

See the advantages and needs while often missing or overlooking the tough part

- Remain often a pure exercise of documentation and validation for process
- No plan for supporting activities
- Often limited to pure QA / Compliance requirements while it is a Business exercise with Compliance implications
- Implication beyond TT exercise
- Often No plan beyond transfer available

Things can go wrong in real life and real issues may come latter during filing , operations and inspection

- Missing documents, information and support for Filing
- Missing knowledge and data for justification and resolution
- Facing Out of Compliance
- Loosing Commitments and Knowledge

Leading to a lack of Sustainability



Be Aware of Pitfalls and Impacts on Future While Transferring during Development

Miss to recognize need for TT during development

- Lack protocol when done too early
- Non validated process – vague or no acceptance criteria and process is different
- Loose Development history link



Development performed purely externally in CMO

- How to transfer to another CMO in the future for scale up, for manufacturing or for back up
- High risk for comparability or bridging study
 - Transfer biologic from small scale to large scale,, different CMO's, different process and molecule and need for comparability and new clinical trials

Lack industrial competence internally or lack knowledge to transfer to CMO, rely purely on CMO

- From CMO to CMO, no competence internally for filing
- How will you build your file and secure compliant supply

Pitfalls during Transfer for Operations May Jeopardize Sustainability of Long Term Supply

Miss or Overlook differences in Operations during Transfer

- Different equipment, systems/operations, scales
- Different utilities
- Different suppliers
- How much to describe and what to describe?
- How to manage these differences?

Lack Knowledge support to secure successful Transfer

- Lack industrial expertise (senders) and product knowledge (receiver)
- Lack knowledge to justify deviation

Lack to secure system suitability and process capabilities before starting TT

- Critical for Biotech product including Media prep, sampling, ancillary
- Active support for missing information not described (Know how)
- Train operators and perform trial runs

Transfer of Methods may be Overlooked or Missed with Significant Impact

When transferring process, what about methods?

Transfer internally? Outside? CMO?

Methods and Stability Critical to transfer therefore often decision not to transfer

- What about shipment validation, stability handling?
 - Methods not transferred and shipment not validated with high risk to product
- What about storage and Management to secure continuity?
 - Stability transferred without clear Go live plan – high risk for compliance

Lack Plan for Operations to Go Live beyond TT

TT to a CMO May have Significant Impact on Your Future Business

When selecting a CMO think out-of-the-box:

- What could go wrong in your relationship?
- Change management, change ownership, loose competence, stop production

Lack of knowledge on your product for investigation and assessment of deviation

- Where is the knowledge and support

Your process may be jeopardized by other products and stopped

- Contaminations
- Compliance issues: Failed inspection or Warning Letters – no resources available to transfer asap to secure supply

Receiving Company may decide to change or stop Operations

- Change technology and stopped production no other supplier available
- no possibility to transfer leading to removal of product

Think Forward into the Future with Ultimate Goal in Mind to Define Scope

Think beyond technology and Focus on Ultimate Goal:

- Filing and Approval
- Continuous Supply
- Full Compliance

TT must be considered as a part of a continuum from past to future

- Must get aligned with past to support future
- How will you justify product supported by Historical data in case of differences

Consider Sustainability of Operations beyond TT

- Perform sustainability analysis up to file and inspection and operation

Sustainability Analysis needed to secure your future business beyond TT

Real issues may come latter during filing , Operation and Inspection with significant business impact

- Fail registration, Fail Inspection
- Lack supply, Stop product

Sustainability analysis will define the scope of the TT and beyond

- Go beyond TT risk analysis - Not limited to what can go wrong during execution
- Think options - how will you manufacture in the future and needs for futher transfer in the future

What is Long term view for sustainability of the business

- How will you justify difference during filing
- Which additional study needed - comparability or bridging study
- What organizational needs - who in charge during and after TT – Man in plant
- What needs for future transfer and capacity
- How CMO will cooperate, support supply despite difference in priorities
- How to access data, knowledge for filing, inspection, Operation and future transfer



In Conclusion, Sustainability of the TT is Critical to Secure Future and Reach your Business Goal

Recognize TT as a Strategic Exercise

TT Engage the Company for the future

Must keep future and Goal in mind at all time

Perform Sustainability Analysis to secure future supply as Goal does not stop at the TT

Key Learning and What to Do and Consider

Bad Transfer/ Incomplete / non compliant

- May require new clinical trial
- May lead to failure to PAI / Inspection
- Failure to Supply

A well organized and managed TT:

- Bring additional capacity
- Competence in process and product
- Flexibility
- Financial advantages

A Step to Reach your Business Goal

