

What for...?

A process or analytical method technology transfer (TT) can take place at any stage of the life cycle of most products: from preclinical development through clinical studies, scale-up and launch to the post-approval phase.

The reason to start a TT can be driven by project needs but also due to strategic management decisions. A transfer of technology can take place internally, within the same company or it can be an external transfer to or from a Contract Manufacturing Organization (CMO) or Clinical Research Organization (CRO).

A key message during any TT is to realize that it is not just an analytical method or process information transfer but it is a know-how transfer. In some cases, the product and process know-how is not fully described in the procedures and this might become a potential risk and gap during the TT phase, adding the risk of losing valuable information.

Facing the challenge...!

A successful Technology Transfer requires a structured and logical approach, awareness of typical pitfalls, clear expectations from sending and receiving unit, and all these driven by an open and trustful interaction within the team members.

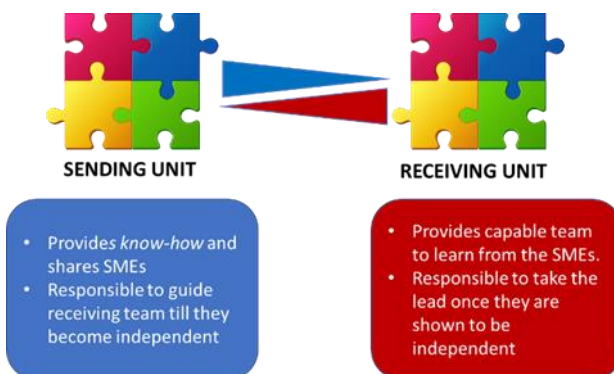


Figure 1. Technology Transfer change in leadership

A multidisciplinary team of experts is key at both sending and receiving sites to minimize any potential TT gap. Senior management should be supporting the TT team understanding the balance between time pressure and the risk of a failed TT.

It is common to underestimate the efforts required for a successful transfer. A TT should be an easy and fast step! In practice equipment, raw materials, people and environment are never the same at two different sites and these differences usually become a challenge to overcome. Hence a good process and product knowledge is key for a successful transfer. This knowledge enables a sound evaluation to identify high risks during the transfer, allowing a good understanding of the differences that should not be compromised during the transfer.

How can we support you during a Technology Transfer?

Progress-PME has a wide expertise in process and analytical methods transfers. We can help you by:

- ✓ Leading the TT team or becoming one of the experts from the multidisciplinary TT team
- ✓ Guiding the team to follow a logical and structured TT process making sure that risks and potential gaps are minimized
- ✓ Defining the success criteria for a TT and evaluating progress against these pre-defined success criteria
- ✓ Sharing tools and templates, such as TT project plan, Bill of Testing, Bill of Materials, Bill of Equipment and TT gap analysis, among others, to facilitate documentation gathering within the multidisciplinary team. Bringing to the table lessons learned from similar experiences to avoid repeating the typical TT pitfalls
- ✓ Organising “deep dive” sessions during which in-depth questions can be asked to, and answered by, the transferring experts. This will minimise the risk of non-documented knowledge not being transferred
- ✓ Setting up and coaching the TT team taking care of obstacles that might block the know-how transfer
- ✓ Executing risk assessments to identify and mitigate risks
- ✓ Proper TT closure making sure all the key information has been gathered. These will be required for any dossier update and any future audit

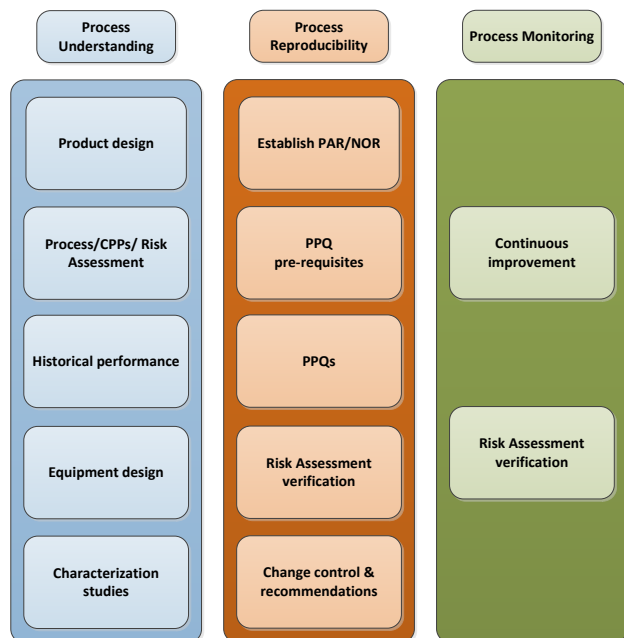


Figure 2. Process Technology Transfer step

Typical Technology Transfers pitfalls

- ✓ Lack of clear roles and responsibilities from sending and receiving units
- ✓ Misaligned expectations from sending and receiving units
- ✓ Adopt shortcuts due to time pressure without a clear understanding of the potential risk and impact
- ✓ Missing to involve key stakeholders from the beginning, e.g. regulatory affairs team
- ✓ Weak documentation management: review and approval cycles unclear, final documents archive missing
- ✓ Weak conflict management approach: usually a technology transfer takes place under time pressure and within multidisciplinary teams with different backgrounds. These factors usually trigger a lack of an open communication causing frictions when not resolved

Track record and facts

This is a summary of our main Technology Transfer experience:

- ✓ We have been leading several transfers for large, small and CMOs within pharma organizations, covering process and analytical methods transfers
- ✓ Our project managers, leading project teams consisting of external resources, have lead several internal TT's from the project team to the internal line organisation
- ✓ We have allocated experts to become part of the TT team in several technology transfers
- ✓ We have developed several tools and templates to facilitate the transfer process following good documentation practices
- ✓ We have shortened TT timelines for completion based on previous learnings and typical TT pitfalls
- ✓ We have supported organizations training employees to follow TT good practices

Who are we...?

Progress-PME is an independent Project Management and Consultancy Company with customers in life science, (bio)pharmaceutical, medical device and healthcare industries.

The company was founded in 1999, operates internationally and provides support throughout the entire range of process development to commercial production.

Progress-PME provide services in the field of project and interim management and Consultancy.

Fields of expertise: CMC, Quality (cGxP), Validation, Engineering, LEAN Six Sigma.