



# Guide to a Successful Drug Development Technology Transfer

Steps to Conducting an Efficient and Effective Technology Transfer

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# Introduction: Why Technology Transfers Occur, and the Importance of Project Management

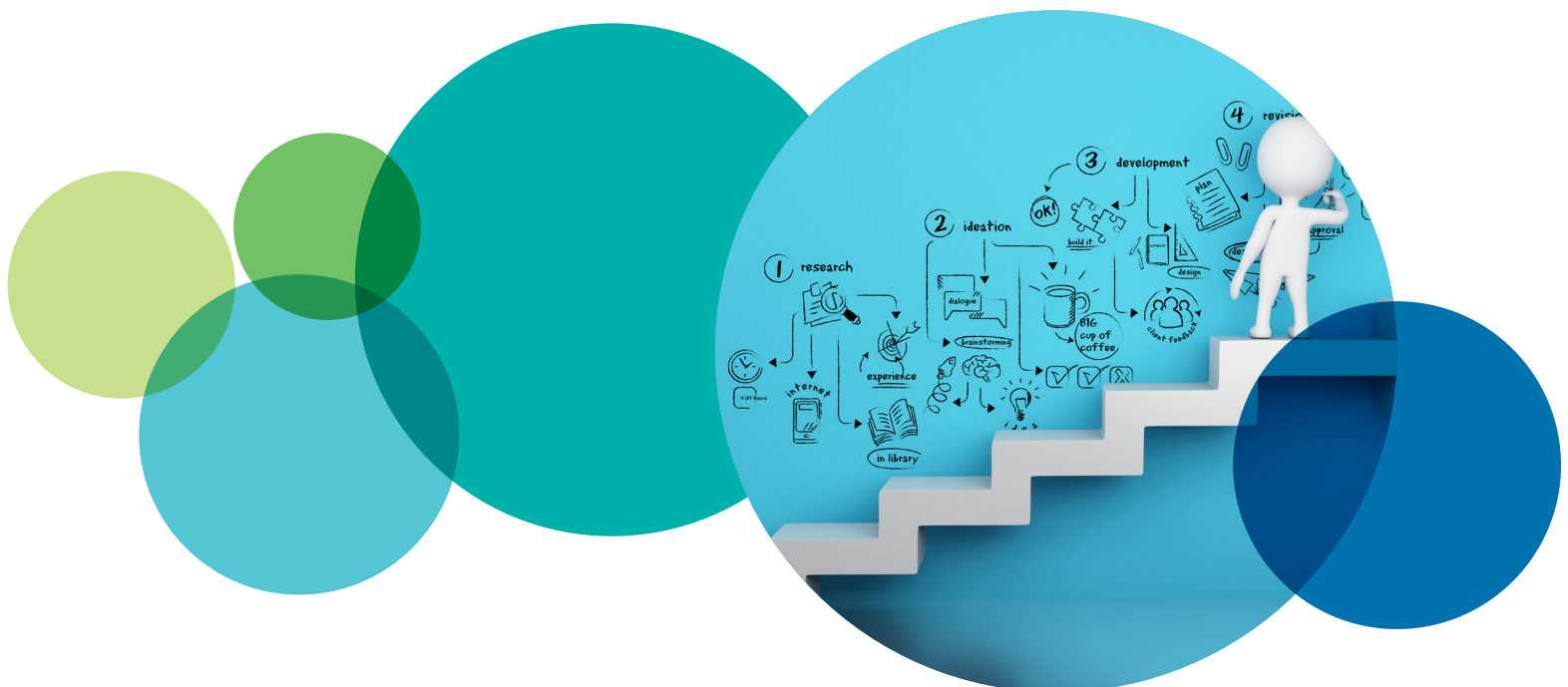
During a drug development technology transfer, the focus is on moving products from one manufacturing site to another while preserving process and product integrity. Ultimately, the goal is reaching the commercialization of the drug product. These are complex projects that require a high degree of pharmaceutical project management experience.

The transfer team must be cross-functional and should include key team members, which will be described in detail below. Because the transfer typically involves a minimum of two locations and perhaps several more, the transfer team provides disciplined coordination during the process and serves as a central repository of information about the transfer.

This cohesiveness is especially important in situations that involve vast geographical distances and multiple languages. There may be a high level of complexity involved in the pharmaceutical development itself, which requires sophisticated technical expertise—and perhaps translation—for all involved parties.

This isn't the type of project that's well suited to a brand-new project manager or someone who is still in the learning stage of their professional development. It takes a project manager with a high level of expertise as well as excellent interpersonal and organizational skills, so keep this in mind as you explore the guide you'll find on the following pages.

This guide will provide insights into the technology transfer process and help your company understand the key elements of a tech transfer. We'll address nine key steps you'll need to take, including conducting these transfers during the COVID-19 pandemic.



# Create a Technology Transfer Plan

As you create the tech transfer plan, formalize it in writing and keep it in a safe, centralized location with credentialed access that maintains security for the relevant data. Make the plan highly detailed with as much input from team members early in the process as possible.

Include input from all departments and visit the existing site or sites in an information-gathering capacity. Ask questions that reveal the issues and roadblocks that may potentially arise throughout a technology transfer.

Visit the new site or sites and work with the team members. Gather information not only from the senior executives but also from the technical teams who are most familiar with the details of the process and equipment. The analytical personnel and engineers from the receiving site must visit the current sending manufacturing site to see how things are done now. Key team members need to understand the differences between the two sites.

The tech transfer plan, at its core, facilitates communication. Here are some of the project management communication factors to take into consideration as you design your transfer plan.

Key project management skills and factors are:

- Serves as the communications nexus
- Should be able to address issues and concerns efficiently
- Acts as a repository of information plus a hub of information sharing
- Will need to prioritize among initiatives, escalate issues, and seek support from appropriate areas
- Manages inputs and outputs
- Provides expertise with both resource management and stakeholder management
- Time tracking against milestones
- Budget adherence
- Risk management and mitigation

The project manager provides the essential service of establishing an effective communications plan and ensuring that all team members and stakeholders receive information in a timely manner. The focus should be on defining the scope of the project, conducting gap analysis, and getting the right team in place to conduct the tech transfer successfully.

A project manager must, at all times, find solutions that work for the company and its team members. They should proactively identify and manage risks and manage issue escalation to remove all barriers as they arise, using the communication channel between the two sites for a successful tech transfer.

# Create a Technology Transfer Plan

Certain team members are almost always involved in a tech transfer at both the transmitting and receiving sites. Identifying and assigning these individuals to the team will take time and will involve reassigning some of their day-to-day activities to free up enough time if team members are not dedicated to the project. These projects may require a large number of team members from a diverse cross-section of company departments.

Key team members from the receiving site will need to be involved in the tech transfer planning process. Team members typically involved in the process include some of the following expertise or functions.

- Analytics chemists
- Chemists
- Core functions
- Engineers
- ERP system specialists
- Labeling and artwork/packaging engineers
- Logistics
- Manufacturing
- Marketing
- Medical affairs
- Operations
- Planning
- Process engineers
- Procurement
- Quality assurance
- Quality control (QC)
- Regulatory specialists
- Sending/receiving at both sites
- Statisticians
- Supply chain
- Trainers

The above team members must be involved in the development of the technical transfer plan at an early stage of the project. They will identify the information that needs to be transferred and the amount of time needed to do so. This team will also be providing estimates of time, cost, and resources associated with equipment setup and qualification, validation batch manufacturing, intermediate and finished product testing, and the creation and approval of protocol and reports. The tech transfer plan will require a preliminary timeline with input from the core and extended teams.

Now that we have begun to create the tech transfer plan, we can look at how the process plan should be laid out at the receiving site. Next, we'll address how this happens and how it involves the technical package.

# Create the Technology Transfer Package

The tech transfer plan needs to include the activities associated with the sending site. As part of the timeline development process, it's time to map out the tech transfer plan at the receiving site and create the technical package for the transfer. The technical package is any technical information that needs to be replicated from the existing site to the new site.

A project manager typically receives only portions of the technical package during the transfer planning process but the planning process should have a rather complete list of information that will be transferred. When the process takes place, the entirety of the transfer package will be transferred.

The project manager will be tracking and facilitating the transfer of technical information like processes, specifications, and qualifications along with ensuring there is a solid plan in place for the replication and transmission of this information.

Common categories of transmitted technical information include:

- Equipment specifications
- Regulatory information
- Previous processes
- Quality control package
- Tolerances.
- Vendor data
- Test methods.
- Operating conditions
- Timeframe constraints
- Product specifications
- Control strategy

Process planning tips from The FlexPro Group:

1. Don't expect this process to be too neat and tidy. It's an ongoing, ever-changing process that occurs over time. The client may not have clearly-documented procedures or practices. A gap analysis will help uncover and address some of the unknowns.
2. Pharma companies are required to adhere to GMP guidelines for drug development and manufacturing which includes having appropriate documentation. Their business is complex and usually requires dedication from the project manager to create full documentation. This is why it is critical for experienced technical personnel to witness how things are currently done.
3. Interpersonal skills are essential here. Connect with the people at the highest and lowest levels of the organization and work on building their trust so they're willing to provide key insights that lead to success.

It should be noted that sometimes, introducing a new process with its associated raw materials and intermediates may require new permits or changes to existing permits before manufacturing can begin. It's important not to miss this crucial step. Additionally, the supply chain should be reviewed for lead time and qualification of new raw materials.

Next, we'll look at the importance of the comparability report.

# Complete the Comparability Report

A comparability report, also known as a gap analysis, examines the technical gaps between the existing site and the new site. It should assess the manufacturing capacity, packaging capabilities, environmental controls, and sampling and testing capabilities. It should occur before the technical package is approved.

The technical documentation package prepared by the sending site is the foundation upon which the receiving site performs a site readiness assessment and the accompanying risk assessment. These assessments, in turn, form the basis of the comparability report. The comparability report is then used to create the transfer plan, timeline, and budget for the tech transfer. In many cases, a final post-validation tech transfer report is never created.

In the comparability report, look at a variety of areas, including manufacturing, packaging, and testing equipment, raw materials, packaging supplies, equipment and infrastructure upgrades, personal protective equipment, and potential changes due to the industry and regulatory environment. In some cases, new and stricter local safety environments require adjustments to meet these higher standards. Make recommendations about adjustments that would need to take place if certain contingencies occur.

This is a key part of the process, and without the comparability report, the rest of the process won't happen smoothly. Prepare a thorough comparability report, and refer to it frequently as the process continues.

The receiving site should make at least one demonstration batch. In addition to the demonstration batch, an analytical transfer process should involve the receiving site and the sending site analyzing samples from the same lot and comparing results.

To be clear, there should be two parallel efforts occurring. One is for the manufacturing process, in which batches are made at the receiving site and are checked by the sending site. The batches should cover all steps of the intended manufacturing and packaging process. The other effort involves testing identical samples at both sites to ensure both sites are getting the same test results.

Based on the comparability report and the other efforts taking place at this stage in the process, it is likely the preliminary timelines and possibly the cost estimates will need to be revised and shared with senior leadership.



# Do a Risk Assessment

The risk assessment is a critical part of the process and should occur early in the process. Risk assessment is a continuous process that lasts for the duration of the transfer. Typically, a risk register is created as part of the planning process and is reviewed and updated throughout the technology transfer project with some risks being resolved and new risks being added, evaluated, and tracked.

Risk assessment enriches the process and helps create a deeper understanding of the process so that all team members - including the highest-level executives who are in charge of resource allotment - can understand what is occurring with the tech transfer and potential risks involved.

It should involve multiple team members, including sourcing, manufacturing, packaging, and more. As the project manager, you can help identify relevant attributes and parameters using input from the experts you've been working with during the earlier stages of the process.

At this stage, the project manager is serving the crucial role of highlighting successes and identifying threats to the stability of the process. In clear terms, document in writing which types of things could go wrong, including any type of disruption that could slow or stop the process.

Rate risks according to their likelihood and describe the potential impact of each risk. Include factors like raw materials availability, manufacturing delays, inaccurate specs, and shifting deadlines that could threaten the transfer.

Encompass all levels of risk, including time-based, technical, and financial issues. For example, if the tech transfer will involve a dangerous process, describe it in detail, and create a contingency plan. This helps mitigate risk for the team members and shows you've done your due diligence in managing the details of the tech transfer.



# Conduct a Test Transfer

The manufacture of test batches and the testing of the receiving site's new capabilities typically occur during the same timeframe. Now let's take a closer look at the testing process.

The testing process involves two sub-steps:

1. Order all necessary supplies, like reactants and raw materials, and allow appropriate lead times.
2. Prepare to test small-scale batches.

Although this is a brief summary of the test transfer process, each of these three steps will take a significant amount of preparation and planning. Help your team members accept and adjust to the idea that the test transfer is a necessary part of the process and sets everyone up for success later when the actual transfer must take place.

Next up, we'll look at the value of master batch records in the pharmaceutical tech transfer process.

## Issue Master Batch Records

At this point, it's time to issue the master batch records that will preserve essential information during the transfer process. Start this step by preparing the receiving site to receive master batch records.

Follow all protocols and specifications, including those that are regulatory. The team's subject matter experts provide a deep well of intellectual resources within the pharmaceutical company. Experts oversee the process and look for issues on both ends, at the existing site and the new site. Remember to document the entire process down to the small details and note any adjustments that are needed.



# Formalize Training

As the project manager, you have a high-level view of the essential tasks involved and will begin to get a sense of where additional training will be necessary to ensure success. You can also seek the input of your team members on this front.

The formalization of training usually includes the creation of training packages associated with operating new equipment as well as the new manufacturing and testing processes. Retrievable training records and proof of competency must be available for health authorities and auditors.

The workers at the new location will almost certainly need training to cope with the influx of new processes and demands. This includes analysts and operators who are conducting the tech transfer itself.

It also includes people who may not be directly involved with the transfer but will be involved in the future on an ongoing basis, like people who will work around the production line.

Consider using a “train the trainer” approach, where those with firsthand observation of the tech transfer become trainers themselves. Your first trainers will train the second batch of trainers and so on. Soon you have a large pool of trainers who are not only great teachers but have also educated themselves more thoroughly as a result of taking the time to teach the information.

Process validation is next, and it reinforces the validity of your tech transfer process.



# Validate the Process

Now let's look at process validation. While newer, smaller companies may go straight into validation after the test batches are complete, some companies have a gating process before test batches are run and again before validation batches are allowed to begin. Quality assurance is often a critical factor in the approval of validation protocols and giving the final word on moving forward.

Process validation involves creating a protocol that points to and leverages the content of the master batch records. This process resolves uncertainties discovered in the previous steps and wraps things up in an organized way. It also shows the value and validity of the tech transfer process.

What happens during process validation:

- Start with your specifications and develop protocols.
- Manufacture three batches under specified conditions.
- Align on a sampling plan that includes in-process and final samples.
- Quantify what the acceptable results are.
- Determine prerequisites and qualified equipment.
- Set forth the criteria for success in all areas.
- Collect batches, collect data, and create reports.

During process validation, note any deviations that should be investigated. Determine whether deviations are within the acceptable range or if adjustments will need to be made.

Generally speaking, most issues should have been resolved before starting validation. Validation batches are not supposed to have surprises or issues requiring additional batches. On the other hand, outside factors unrelated to the tech transfer - for example, a loss of utilities - may make it necessary to repeat a batch. Document everything thoroughly along the way.

In the next stage, we'll develop the final transfer report as we get closer to wrapping up the transfer process.

# Develop the Final Technology Transfer Report

In this part of the process, the project manager serves the key role of developing the final tech transfer report and delivering it to the client. This is the key document that results from the process and serves as the archive and reference document for the transfer.

It's important to include a high level of detail in this document without forgetting to take a step back and provide a big-picture view of the process. Include a justification for why it took place, and review the parameters that were set forth at the beginning of the project.

Draw overall conclusions, summarize persistent problems, mention future risks, and conclude with a look at the triumph of the project. Sending and receiving units should evaluate the success of the tech transfer through analysis of the product and data. At this point, the project manager ensures that the technology was transferred successfully and ownership has been finalized with the receiving site. This is an opportunity to showcase the value of project management in technology transfers, in achieving project goals successfully.

## A Note About COVID-19 and Tech Transfers

The COVID-19 crisis has highlighted the fact that there is an art to the science of tech transfers. As tech transfers have been urgently required during the development of the COVID-19 vaccine, the value of project management for the life sciences has been clearer than ever.

McKinsey & Company, one of the most respected names in the pharma world, describes today's vaccine tech transfers as a turning point in human history, saying, "How quickly COVID-19 vaccine production ramps up will depend on technology transfer—the capabilities and processes that can speed vaccines from development to manufacturing."

One of the critical components of a fast and successful vaccine tech transfer is subject matter expertise. FlexPro offers strong project management expertise that can help a busy pharma company accelerate timelines while managing a large pool of vital team members and team members.



**"Tech transfer may be critical to beating COVID-19."**

-McKinsey & Company

# For More Information

As you can see from the information presented in this whitepaper, the success of a tech transfer for a life sciences organization depends largely on its project management. With a high level of project management expertise, a company can conduct a smooth and successful tech transfer that supports fast innovation and global human health.

To learn more about tech transfer project management for pharmaceutical companies, connect with the experts at FlexPro. We specialize in serving the project management needs of the world's life sciences companies.

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