3 Key Things To Consider When Choosing A Partner For Your Tech Transfer

Transferring pharmaceutical production between sites can bring many advantages. As well as providing ample opportunity to make improvements to the product or process, a successful tech transfer can greatly reduce risk by securing the supply chain with manufacturing multiple sites, and it can simplify distribution logistics where those locations are in geographies closer to critical markets. Additionally, tech transfer has significant potential to reduce program costs where the selected site offers more economical production.

Despite these advantages, many companies are hesitant to embark on tech transfer due to concerns over possible supply interruptions, program delays, unexpected costs, or regulatory implications as production sites are filed; all these factors can have associated repercussions for patients. This apprehension stems largely from acknowledging that a product or process cannot be guaranteed to behave identically across sites, yet it is counterbalanced by the inarguable fact that tech transfer is readily expedited through clear communication and strong project management. Provided realistic expectations are established from the outset, potential challenges can be identified and addressed early on to ensure tech transfer runs smoothly.

One way of streamlining tech transfer is to partner with a CMO demonstrating a proven track record across the entire drug development and manufacturing continuum. Not only will an experienced CMO partner have the scientific and technical knowhow to resolve any difficult production steps but they will also be able to leverage a comprehensive equipment train to ensure the right tools are used. Moreover, where CMO expertise is backed by robust analytical capabilities and cutting-edge technologies such as modeling and simulation tools, there should no longer be any reluctance to reap the benefits tech transfer can afford.

1. Goals of tech transfer

There are many reasons for pharmaceutical companies to consider performing tech transfer. Paramount among these is the need to ensure an uninterrupted supply of the materials essential to drug production, especially during unprecedented situations such as the global COVID-19 pandemic or natural disasters like hurricanes or earthquakes. As well as providing a safeguard should a key source suddenly become unavailable, spreading suppliers across multiple geographies avoids the inevitable delays associated with identifying and qualifying an alternative source if restrictions impact a particular region.

Another impetus for tech transfer is a requirement to simplify distribution logistics, especially in the face of mounting pressure on the pharmaceutical industry to enhance the safety, security, and continuity of the supply chain. Product authentication and tracking hinges on the ability to reliably monitor product movements and can be enhanced by reducing the number of supply chain partners and having those partners located in close proximity to critical markets.

Tech transfer may also be an effective means of reducing costs – either by moving production closer to geographies where demand is highest or to a site able to manufacture more economically. Lastly, tech transfer offers significant opportunity to improve the product or process being relocated. This involves developing a comprehensive data package prior to transfer and includes identifying and filling any information gaps to establish optimal conditions that meet designated standards for quality and yield.

2. Tech transfer challenges

The two main challenges of tech transfer concern the equipment train and knowledge transfer. Even where two sites are using the similar equipment and operating procedures, it can never be guaranteed that a product or process will behave identically across both. The more similar the equipment train between the two sites, the more similar the drug products across sites will be, potentially reducing the regulatory burden of filing a site change. However, standardizing equipment across sites can only go so far toward ensuring consistency and it is essential that critical process parameters – especially those most likely to cause variation - are known as early as possible. Equally important is the transfer of the analytical methods as this is ensures the quality of the product.

Capturing the expertise of the personnel involved in the transfer (i.e., the knowledge transfer) can be another pain point. Although a complete information dossier should be provided at handover, it is often the case that key details are missing, unclear, or difficult to find. Moreover, while the sender may have experience of the product or process spanning many years, the receiver may be able to augment that knowledge by applying expertise garnered from other programs. For tech transfer to run efficiently, it is vital that the knowledge of both partners is leveraged through a close and transparent relationship.

Balancing the time and expense of tech transfer against the long-term benefits on offer is a further consideration. While substantial investment is required to plan and execute any tech transfer, cutting corners by assuming the product or process will mimic a similar transfer that has been performed previously is invariably a false economy. Only by treating each program as unique, and with both parties being accommodating of change, can tech transfer stand a realistic chance of first-time success.

3. Approaches for success

Tech transfer requires a CMO partner with long-standing expertise in drug development and manufacturing. This means a partner employing predictive approaches (first principles models, engineering calculations, and simulations), experimental approaches (process understanding, placebo experiments, and process analytical technologies), and a combination of both (dimensional analyses, small-scale equipment, statistical experiments, data-based modeling, and materials science) within their process and engineering sciences toolkit.

In recent years, modeling has increasingly been used to streamline tech transfer, not least because it reduces the amount of overall experimentation required. By promoting more efficient and scientifically guided experimentation, modeling tools promise faster development, more robust processes and, as a result, more scientific regulatory submissions. For example, advanced computer modelling of processes such as hot melt extrusion can be used to help guide experiments, resulting in fewer trials and more robust transfers.

The use of simulation has also become more widespread during scale up and transfer, allowing the process to be investigated using lab-scale simulators or advanced computational simulations, building confidence before running at scale. For example, during tech transfer of an existing tableting process, a compaction simulator might be used to confirm the correct settings for the new tablet press by simulating the originating press profile and adjusting compression parameters to maintain key tablet attributes (e.g. solid fraction, density distribution, and tensile strength). This would pave the way to testing such as micro-CT to confirm tablet density and look for cracks and hardness testing to evaluate tablet strength, followed by computer modelling simulations to predict density distribution. Because the simulator makes one tablet at a time and is highly reproducible, using the physical simulator in combination with computer modelling

minimizes the amount of material needed to perform each evaluation yet helps confirm that the proposed process on the new tablet press will produce equivalent tablets.

Another major advantage of combining modeling with simulation is that it enables rapid identification of areas where small changes can be beneficial. For example, whether the use of pre-compression force is sufficient to reduce tablet sticking, or if the extrusion rate will impact extrudate quality. Modeling and simulation also lessen the resources needed to support a transfer, helping to manage costs while ensuring a robust process downstream - a thousand simulations can be used to narrow down to a handful of pilot scale trials, allowing confirmation of process settings with a minimal number of commercial scale trials.

Your partner for tech transfer

CMO leverages a wealth of experience, cutting edge equipment at varying scales, to enable a broad range of tech transfers. To benefit from improvements to your product or process, enhanced security of supply, and greater agility in responding to fluctuating market demands.

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