Tergus Pharma
Think Topicals, Think Tergus

KEYS TO A SUCCESSFUL TECH TRANSFER FOR TOPICAL PHARMACEUTICALS

When looking to do a technical transfer of a topical drug product, it is important to understand the steps needed to create and follow an effective and efficient technical transfer process. There are several necessary elements to achieve a successful tech transfer, including supply chain, raw materials, equipment equivalency, resource timing, communication of structured milestones, quality systems, and relationships with regulatory agencies. These are all factors to consider when defining the right process and selecting a manufacturing partner.

This whitepaper will illustrate

1. Keys to choosing the right manufacturing partner.
2. How to manage a topical drug tech transfer.

First Things First: Choosing the right partner

1 Why are We Doing This?

In addition to understanding a prospective partner's capabilities, it is also important to know the reason for doing a tech transfer. Is an increase in capacity necessary due to growing market share? Are clients or market forces putting pressure on delivery dates and requiring faster turnaround times for current batches? Internal discussions or decisions regarding the transfer should be holistic and include perspectives from operations, quality, sales, and management with the end purpose in mind.

From there, the next step is to get a better understanding of what the technical capabilities of any potential partner might be in light of that end purpose. Some topical formulations can be quite complex, so perhaps there is a need for automated functionality in order to remove potential human errors. If so, it would be wise to find out if a prospective manufacturing partner has experience handling topical drug dosage forms such as ointments, creams, and liquids. There is not a wide range of CDMO's with depth and breadth of experience in that space, so experience with the dosage form (or lack thereof) is important to know.

Does the partner have method validation experience in topicals? Just as some topical formulations can be difficult to manufacture, they can also present unique problems for method development. It is critical to get the right extraction process for a particular assay or to identify a particular impurity for the commercial validation to be successful.

Knowledge and technical capabilities in the topical space are paramount because the decision-making around that can lead to success or failure right out of the gate. And because timelines are also critically important to the tech transfer process, they should be mutually understood right from the beginning. One way to do that is by interviewing the manufacturer's project manager (PM) and/or technical lead who will be handling the product tech transfer and ensure that they have sufficient breadth and depth of understanding. The efficacy and clarity of that person's communication (or lack thereof) will set the tone for the entire tenure of that project.

2 How Prepared are We?

Besides looking externally at a prospective partner's capabilities, looking internally is equally important. Internal records and resources will be critical—are the resources available to help manage the transfer of technical expertise? Is there sufficient internal method validation understanding for the receiving laboratory to execute proper analysis? There should be enough knowledge, resources, and documentation to ensure that the manufacturing leader on the other side can consume that batch process without any major difficulties.

In addition to the short-term factors outlined above, another key to success is to understand long-term timelines from the get-go. Ensuring sufficient manufacturing capability requires knowing how much capacity will be needed short-term, over the following year, or for several years. This should be outlined in the manufacturing agreement. There are many ways to ensure commercial product delivery for years in advance and having a manufacturing partner with a solid manufacturing tenure and financial history will help ensure successes.

3 The Past Informs the Future

Supply history is something else that can be looked at as a part of the initial due diligence—understanding whether or not the industry recognizes this potential partner is an easy way to verify the success of your tech transfer and the ability for that commercial product to be delivered successfully over time. Look at not only the supply chain history, but also the company's financial history to help determine its long-term stability.

Another important piece of the puzzle is looking at regulatory history. Any potential manufacturing partner must have a good regulatory history, and not just with the agency in the country where manufacturing is located, but also with any agency where their product is being delivered. In addition to publicly available information online, employ customized research and schedule an internal audit that will be held at that facility to fully understand the quality management systems that are used to help perform the checks and balances needed for successful tech transfers.

Finally, it is critical to ensure that a clear and concise quality agreement is put in place from the very beginning. This will help define remediation should a quality issue arise, as well as outline qualification of raw materials and components from the various suppliers. This suggestion is not unique to topical drugs, but one aspect that is unique to topicals is that lead times can be quite long for some topical-specific components such as tube manufacturing. Of course, consideration must be made for excipients and APIs, just like other drug product manufacturing, but tubes and other topical-specific packaging can be a pinch point without having robust supply agreements and the right approved supplier up front.

Let's Do This: How to manage the tech transfer process

1 Write it Down

One of the most important aspects of a successful tech transfer is to make sure that every role and responsibility related to the process is defined clearly and concisely. One of the best ways to do that is to establish a project charter. The project charter should clearly lay out project expectations, goals, time frames and timetables, and key milestones within the project. Additionally, it should define the leadership on both sides of the project—the sending side as well as the receiving side. The escalation process should also be documented, as well as who will be making decisions throughout the course of the project. Without establishing this clear definition early, the ambiguity can ultimately lead to missed milestones and backtracking, which results in schedule challenges and unhappy stakeholders on both sides.

Governance can be established using master service agreements, quality and/or technical agreements, but within the project team roles must be clearly defined for who is responsible for method transfers, and who is responsible for providing the required technical packages. Ownership needs to be established for all the various pieces that have to fall into place. Without clear ownership, the project will languish, timing challenges will quickly arise, and everyone will be playing catch-up—never a good place to be.

Budgeting is always a critical part of every project as well. In addition to knowing what the budget is, ensure that mechanisms are in place to keep track of spending. Generally speaking, tech transfer budgets are milestone driven, and those milestones are keys to clearly knowing exactly how successful the process is in terms of both time and budget. Knowing where things should be at a particular time in the project will provide early visibility to slippage, which informs decision-making for possible remediation plans to stay or get back on schedule.

2 Know Your Team

In order to successfully manage the tech transfer process, several different departments from both the sending and receiving sides need to be involved. Representatives from all of those departments on each side of the table need to be a part of the plan, whether it is method transfer or quality control, to make sure that those methods of transfer and validations are done well and on-time so that the project can move forward.

A RACI table is an excellent place to start, which can help clearly define responsibilities, who makes decisions, and who is being informed, to minimize indecision and questions that can negatively impact timetables. It is very important to be clear on who is going to do what, when decisions need to get made, and who is responsible for those decisions.

3 Communication Really is Key

While it may sound obvious, communication really is central to the tech transfer process. The nature of tech transfer requires sharing a tremendous amount of knowledge between parties, so clear communication is critical to sharing that knowledge intact from one team to another. Communication should always be transparent. It should be candid. It should be collaborative. Challenges and problems must be brought to the table and discussed—nothing should be glossed over or ignored. It is often the small details that cause disproportionate trouble during a project.

Meetings should always have established agendas. Meetings should be set in advance. Ad hoc meetings can be held if an issue arises, but there should be a set meeting schedule and a set core group of attendees that need to be at every meeting. Other team members can then be brought in depending upon timing and status of the project, as well as what is planned to be discussed at that meeting.

One reason why it is important for agendas to be communicated in advance is so that people are prepared when they arrive at the meeting. It is also important to take meeting minutes and distribute them promptly to the meeting attendees so that there are no misunderstandings about decisions that were made, actions that need to be taken, and what the next steps are for the project.

The importance of exercising good meeting management can't be overstated. It is too easy for status meetings to morph into working sessions. If this is allowed to happen regularly, the project will suffer. Working sessions need to take place outside of pre-scheduled status meetings. Leaders for the various elements of the tech transfer should do their work up front and come to the meeting prepared with status updates. More importantly, issues, roadblocks or problems need to get resolved as quickly as possible so that team members can keep the project on track as opposed to working through the details while sitting in a status meeting. It really should be dealt with outside the regular status meetings. If a tech transfer team finds itself falling into that trap, then step back, regroup, and reset the expectations for the team.

Solving problems is not the same as communicating problems, however. Nobody likes surprises, so prompt and straightforward communication is important so that issues get raised sooner rather than later. For example, if the purpose of the tech transfer process is transition to a commercial supply, milestones should be set around the prerequisite data for anything that supports the regulatory submission. Begin with a clear, targeted date for commercializing the product and then schedule backwards keeping in mind all the various phases that must happen. The regulatory element is probably the one over which the team has the least control, so be sure to constantly look at the data being generated so that problems can be identified and communicated quickly.

4 Unique Challenges for Topicals

As mentioned previously, for topical products it is important to understand filling requirements from the beginning to avoid delays later. Likewise, if IVRT or IVPT data are required for the tech transfer then move those processes to early in the project life cycle. Otherwise there is a risk of making batches that cannot be submitted until the requisite data is available to support the submission.

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About Tergus Pharma :

Tergus Pharma is an end-to-end service provider for topical pharmaceutical products supporting early phase research and formulation, drug development, testing, and both clinical and commercial manufacturing at our new 100,000 sq. ft. state-of-the-art facility in Durham, North Carolina. Tergus has developed a reputation for delivering quality results to clients for topical/skin semi-solids and liquids as well as other non-skin semi-solids and liquids for vaginal, rectal and otic/ophthalmic routes of administration. With industry-recognized leadership and expertise in method development, such as IVRT and IVPT for topical pharmaceuticals, Tergus also provides clients with peace of mind and helps them to de-risk their product development, tech transfer, and manufacturing activities. Exclusively focused on topical development and manufacturing, Tergus brings the scientific expertise that helps our clients achieve the right balance of scientific know-how, speed of results, and quality, warranting our company motto, **"Think Topicals, Think Tergus."**

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Mr. Payne has over 20 years of pharmaceutical manufacturing experience with a focus on quality and regulatory compliance. At organizations such as Barr Labs, Teva Pharmaceuticals, and Alcami Corp., he successfully delivered global CDMO quality leadership supporting multiple pharmaceutical facilities in testing, manufacturing, and packaging—from product development to commercial product lifecycle phases. He brings a high level of competence in regulatory agency communications and team leadership as well. Mr. Payne graduated from Hampden-Sydney College with a B.S. in Chemistry and serves as an active member with ISPE, PDA, and Quality & Technical Committee with PBOA.

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Mr. Cobb is a senior level executive with over 30 years of experience in the pharmaceutical industry leading technical operations teams with companies such as Teva, Osmotica, Qualitest, G&W Labs, and Cosette Pharmaceuticals. He has direct experience with several dosage forms but focused on OSD and semi-solid products in the generic marketplace. He has a strong record of raising operational performance through quality improvement and analysis of operations and processes, while also reducing and controlling costs. Mr. Cobb focuses on customer service, continual process improvement, personnel, and team development. Mr. Cobb graduated from the University of Nebraska-Lincoln with a B.S. in Engineering.