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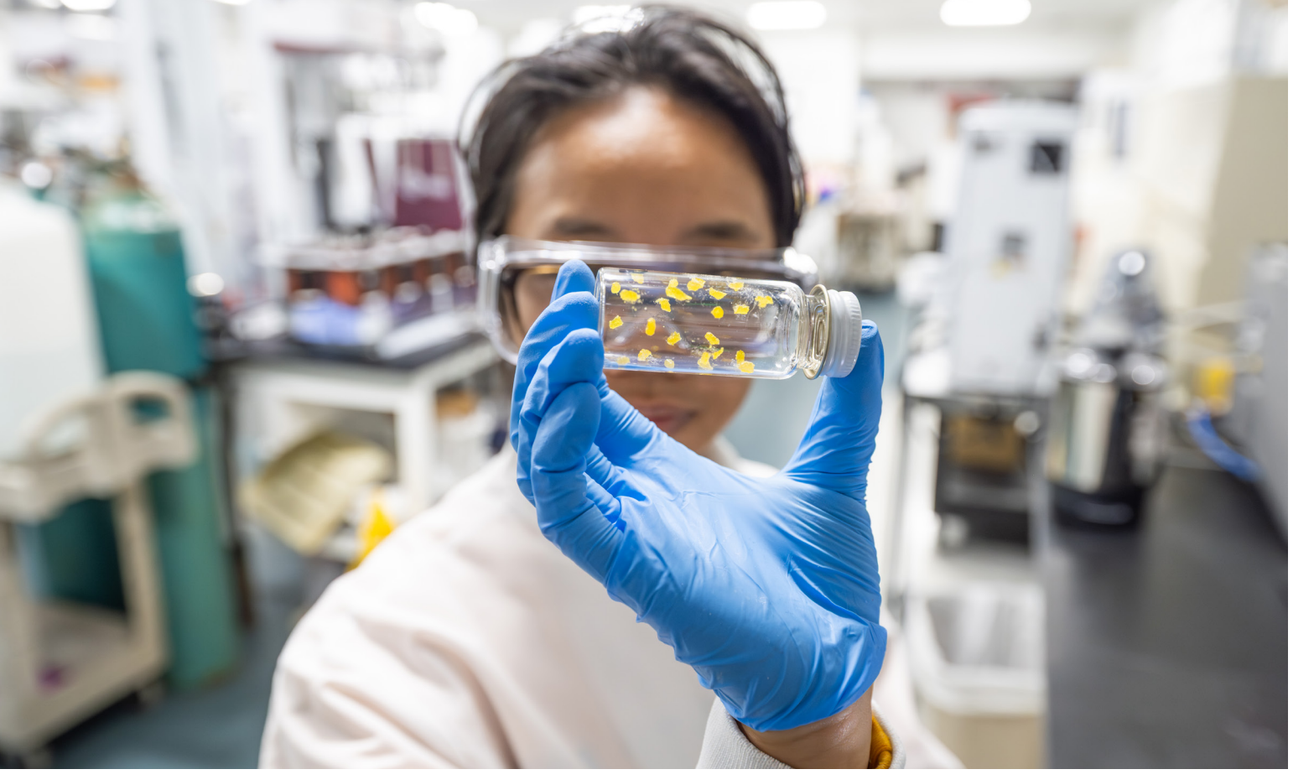
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+ CHOOSING THE RIGHT PATH TO COMMERCIALIZATION

A decision framework for development, tech transfer & ANDA strategy

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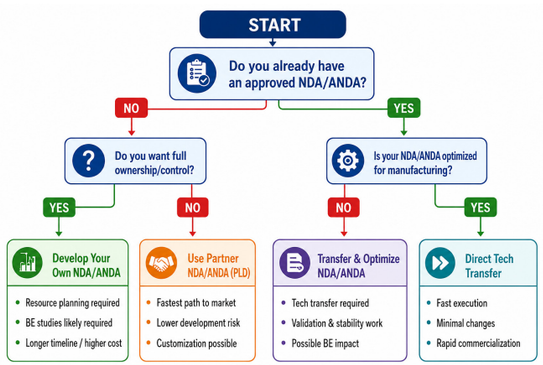
Choosing the Right Path to Commercialization

Innovative Ways to Expand Your Brand Portfolio and Bring New Products to Market

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For pharmaceutical companies, the path from product concept to commercialization has become more complicated, more expensive and more strategically important than ever. The old model was relatively straightforward: When a company wanted to bring a new product to market, it developed the product, filed the FDA applications, waited for approvals, and then either scaled it up at its own manufacturing site or transferred it to a CMO if it wanted to use contract manufacturing.

Today the paradigm has shifted. Companies are balancing speed to market, regulatory risk, development investment, intellectual property strategy, supply reliability and dosage-form differentiation. Branded companies may not have the flexibility to wait several years and spend millions of dollars to commercialize a new product. A company with an approved drug product may need a new manufacturing partner, but the transfer may also present an opportunity to optimize an outdated process within current SUPAC guidance. Others want to extend a brand into a new dosage form or flavor or have only an idea and need help determining the best dosage form or regulatory pathway.



The question is no longer simply, "Can you manufacture this product?" It's "What is the smartest path to commercialization?" At PLD Pharma Services, we use a commercialization decision tree to help customers answer that question. Because each pathway carries different implications for cost, time, regulatory requirements and technical risk, making the right decision at the outset can save months of development time.

EVERY STRATEGY STARTS WITH THE SAME QUESTION

The decision tree begins with one question: Does the customer already have an approved NDA or ANDA? The answer determines the regulatory options, development strategy and commercialization pathway. Customers often arrive convinced they need a transfer or a new application, but once the business objective is clear, a faster or lower-risk alternative frequently emerges.

From there, the options generally fall into four paths: developing a new application, leveraging a partner's existing portfolio, transferring and optimizing an approved application, or executing a direct technology transfer.

PATH ONE: DEVELOPING YOUR OWN NDA/ANDA



In PLD's Analytical & Research Lab, scientists characterize formulations, evaluate stability and dissolution profiles, and develop validated analytical methods to support product development and regulatory submissions.

Developing a proprietary NDA/ANDA still makes sense in many situations. Ownership can be strategically important, especially for companies building a long-term product portfolio. When a customer owns the application, it controls the formulation, supply chain, manufacturing strategy and future lifecycle opportunities, which can create significant commercial value.

But developing an NDA/ANDA is a major scientific, regulatory and financial undertaking. Formulation scientists evaluate excipients, manufacturing processes, dissolution profiles and stability. Analytical chemists develop and validate the methods needed to characterize the product and support regulatory submission. Process development teams translate laboratory success into a scalable commercial process. Stability studies, validation batches and bioequivalence work must be planned and executed. The resulting application then moves through regulatory review before commercial launch can begin.

Modified-release products introduce additional formulation and process complexity, which is discussed later in this article.

The economics of new product development also matter. For certain new OTC products that require an NDA, the FDA filing fee alone can approach $4.5 million before considering formulation development, analytical work, pilot manufacturing, stability, bioequivalence or commercial scale-up. Even when the regulatory pathway is different, the broader point remains: developing a new product from scratch requires substantial investment before the first commercial sale.

That investment may be justified. But it should be made deliberately, with a clear understanding of the business case and the alternatives.

PATH TWO: LEVERAGING A PARTNER'S PORTFOLIO

For companies focused on speed to market, an existing approved NDA or ANDA can eliminate years of development while providing a proven regulatory and manufacturing foundation.

PLD's portfolio offers more than 60 approved ANDAs, with additional products in the regulatory pipeline, and more than 600 OTC products across multiple dosage forms and therapeutic categories, giving customers a faster path to commercialization without having to develop products from the ground up.

That does not mean the commercial product must be generic in appearance or positioning. Existing approved products can often support customer-specific branding, packaging and, where appropriate, product modifications. Flavor changes are a good example. A customer may have a specific sensory



Dissolution baths in PLD's R&D lab help scientists evaluate how different formulations dissolve over time, providing critical data to optimize product performance before commercialization.

profile in mind, but if the underlying application can support the change, the path may be far more efficient than transferring an entirely different application or developing a new product.

One branded customer believed transferring its own application was the only option. After reviewing the product, we concluded that transfer would likely require additional bioequivalence work and preserve an inefficient manufacturing process. Because PLD already held an approved ANDA for a similar product, we leveraged our existing formulation and adjusted the flavor system to achieve the customer's desired flavor profile. The result was a simpler regulatory path that met the same commercial objective.

That is the purpose of the decision tree. It allows the conversation to shift from "How do we execute the path the customer requested?" to "Which path best accomplishes the customer's goal?"

PATH THREE: TRANSFER AND OPTIMIZE YOUR NDA/ANDA

When a customer owns an approved NDA/ANDA, transferring it to a new manufacturing partner may be the right path. But transfer does not always mean exactly copying an old process.

Many approved products have been manufactured for years. During that time, equipment changes, production volumes change, raw material suppliers change, and manufacturing technology evolves. A process that was appropriate when the product was first developed may no longer be the most efficient, cost-effective or robust way to manufacture it.

Technology transfer often creates an opportunity to modernize legacy manufacturing processes. One immediate-release product, for example, had been manufactured using an older blending process. The product performed well, but the process had become expensive and inefficient. Rather than simply reproduce the legacy process, our development team evaluated the manufacturing science behind it. The goal was to match the same level of API homogeneity using a more efficient and streamlined equipment and process train while remaining within SUPAC guidelines.

Because the changes were managed appropriately, the transfer could proceed through a CBE filing without triggering a more time-consuming and costly regulatory delay. The customer gained a more efficient process without changing the essential product performance.

That type of project requires more than manufacturing capacity; the CDMO must understand formulation behavior, equipment equivalency, process parameters, analytical performance and regulatory expectations. The goal is not change for the sake of change, but to create a more efficient, scalable and sustainable process.

PATH FOUR: DIRECT TECHNOLOGY TRANSFER

In other cases, the right answer is a direct transfer. If a product is well understood, the documentation is complete, and the manufacturing process is robust, the most efficient path may be to reproduce the existing process as closely as possible at the new site.



Automated analytical testing provides the data needed to optimize formulations, validate methods, and support efficient product development from concept through commercialization.

Even then, technology transfer is rarely just a paperwork exercise.

A batch record can describe the formal process, but it does not always capture everything that happens in a manufacturing environment. Products that have been manufactured in the same plant for years often accumulate institutional knowledge. Operators may know to make small adjustments, clean between certain steps, monitor a material in a particular way, or recognize when a process is behaving slightly differently than expected. Those details may never be written down because everyone in the original facility simply knows them.

One transfer illustrated this clearly. The customer had manufactured the product for some time, and the batch record appeared complete. Yet during transfer, the process did not behave the way the documentation suggested it should. Eventually, the team had to observe the process at the original manufacturing site to identify the missing nuance. It was not a major formal step, but it mattered.

That is why direct transfer still requires scientific engagement. A manufacturer can follow a batch record. A CDMO with formulation, analytical and process expertise can ask why the batch record works and what may be missing when it does not.

WHY SCIENTIFIC DEPTH MATTERS ACROSS EVERY PATH

The decision tree helps identify the right commercialization pathway, but the success of each path depends on the scientific depth behind it.

Whether developing a new NDA/ANDA, leveraging an existing one, optimizing a process or transferring a product directly, technical questions will arise. A granulation may not reach the expected loss on drying. A raw material may behave differently from supplier to supplier. An analytical method may not perform the same way in a new laboratory. A modified-release tablet may show a dissolution shift after compression. A flavor change may appear simple commercially but require careful formulation work to preserve product performance.

Those questions cannot be solved by manufacturing alone.

At PLD, formulation development and analytical development are integrated with manufacturing. The R&D organization supports solid oral dosage forms, liquids, semi-solids, gummies, medicated gums and complex modified-release products. That breadth matters because customers do not always come with a finished technical solution. They may come with a commercial goal: improve compliance, add a flavor, create a line extension, enter a new category, or solve a manufacturing problem. Experience across dosage forms allows the team to think creatively instead of forcing every product into one technology platform.

It also allows technical problems to be solved faster. When formulation scientists, analytical chemists, process development teams and manufacturing personnel work together, issues do not need to be handed off repeatedly to outside resources. The people who understand the product are involved when the process is being developed, transferred, optimized and manufactured.



Small-scale pilot manufacturing with short turnaround times allows for more extensive process characterization using Design of Experiments (DoE) to support FDA Quality by Design (QbD) expectations. Because our pilot equipment operates on the same principles as our commercial manufacturing lines, scale-up is faster and more predictable.

MODIFIED-RELEASE PRODUCTS CHANGE THE EQUATION

Modified-release products deserve particular attention because they introduce unique scientific and regulatory considerations.

With an immediate-release product, transfers can be relatively straightforward, especially when the formulation and process are well understood. With modified-release products, the release mechanism is part of the product.

Polymers, coatings, pellet characteristics, compression forces, processing conditions and equipment can all influence how the drug is released in the body. In those cases, development is not simply a matter of matching ingredients. It requires understanding how formulation and process variables affect in vivo performance.

Changes in equipment, coating parameters, pellet characteristics, compression force, polymer behavior or processing conditions can affect the release profile. For that reason, modified-release transfers frequently require new bioequivalence studies to demonstrate that the product performs as intended.

Those studies add real time and cost. Depending on the size, design and location of the study, a bioequivalence program can add roughly six to twelve months. Conducting a study in the U.S. may be faster in some situations but can cost several times more than conducting one overseas. Overseas studies can reduce cost but may introduce additional logistical challenges, including sample shipment, documentation and several months of preparation. The right choice depends on the business case, timeline and risk tolerance.

Pilot bioequivalence studies and IVIVC can provide predictive information before pivotal studies, reducing technical risk and improving formulation decisions.

Anything can happen once a product enters the human body. The more that can be learned before the pivotal study, the better positioned the project is for success.

THE CDMO AS COMMERCIALIZATION PARTNER

Customers are no longer looking only for manufacturing capacity. They are looking for partners who can help evaluate development strategy, regulatory options, dosage-form choices, analytical requirements, technology transfer risk and commercial timelines as connected decisions.

That shift is especially important as development costs rise and companies look for more efficient ways to bring products to market. Large, branded companies and emerging brands are all asking similar questions: Do we need to develop this ourselves? Is there an approved product we can leverage? Can a legacy process be modernized? Will this transfer require a bioequivalence study? Is there a faster path that still meets the commercial objective?

Those are not purely manufacturing questions. They are commercialization questions.

The smartest path is not always the most obvious one. The decision tree is useful because it creates a disciplined way to ask those questions. It helps customers understand that there may be multiple paths to the same commercial objective and that each path carries different implications for time, cost, risk and control.

Pharmaceutical companies need partners who can evaluate the full commercialization strategy, from regulatory pathway and dosage form to technology transfer and lifecycle optimization. The right pathway can shorten timelines, reduce cost and lower risk.

Choosing the right pathway may be the single most important commercialization decision a company makes.

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