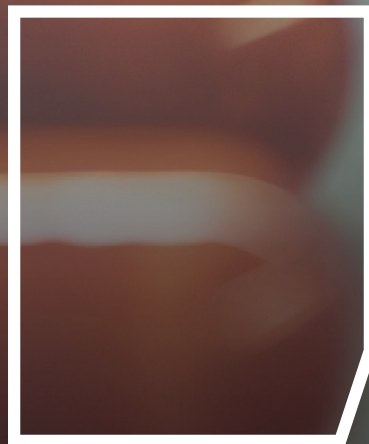


Scaling success:

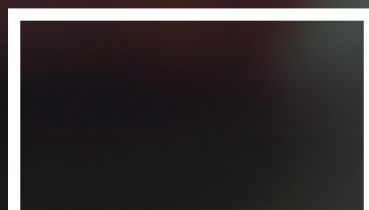
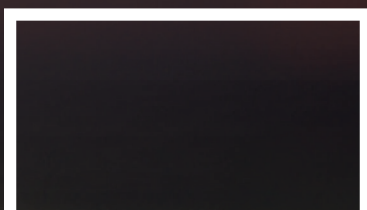
Mastering modern challenges in drug development through expert technology transfer



16

Ac

Acumen



In the high-stakes world of pharmaceutical development, time is more than money—it is patients' hopes, outcomes, and lives. The ability to influence these considerations by getting innovative therapies to market quickly can hinge on details so small, they're molecular.

Missing these details during a technology transfer can cost time a patient does not have. Unexpected light sensitivity in formulations can require specialized packaging. Tablet production can be upended because of pain points in powder flow. Hard and fast logo and serialization requirements might drag the final stages of launching a promising pharmaceutical, to the frustration of everyone who worked to make a promising drug a reality.

None of these problems happen in a vacuum. They are all critical steps in drug development and especially in technology transfers requiring advanced specializations that need to be

achieved in order to hit your launch window. Without the required expertise, slowdowns can become dead stops in the tech transfer process.

The right mix of strategy, science, and logistics to achieve a successful tech transfer can be complex to gather. As Thermo Fisher Scientific experts can attest after overseeing hundreds of successful projects, having the right knowledge during the most delicate parts of the process can make all the difference. Let's explore how the interplay of good strategy and planning, material science, digital solutions and packaging expertise can transform promising drug lead candidate results into life-saving medications.



The bottom line of biotech: Streamlining critical areas of a tech transfer

The efficiency of the tech transfer process not only impacts patient access to new treatments, but also carries significant economic implications for the industry.

Studies highlight the economic stakes involved in a tech transfer. According to a report by the Tufts Center for the Study of Drug Development, the average cost to develop and gain marketing approval for a new drug is estimated at \$2.6 billion (DiMasi et al., 2016), with a significant amount of this cost occurring during late development phases, including tech transfers. While the exact savings from efficient transfer processes are not precisely quantified, streamlining this phase can substantially reduce time-to-market and development costs.

The multifaceted challenges in this process can severely impact both timelines and budgets. Common hurdles include analytical discrepancies, capacity limitations, quality control issues, equipment incompatibilities, and communication breakdowns. Each of these factors can delay market entry, resulting in lost revenue and increased development costs.

However, these challenges are opportunities for innovation in the hands of the right partner. A key strategy in addressing timeline concerns is consistency across manufacturing sites. When true harmony between sites is available, the process is not only streamlined, but the additional redundancy can also help speed time-to-market.

To address the multifaceted challenges of tech transfers, a comprehensive methodology focused on predictability and efficiency is essential.



Key components include:

- Anticipatory risk mitigation with real-time monitoring
- Localized project oversight
- Streamlined governance with clear escalation pathways
- Seamless phase transitions striving for “Right First-Time” delivery
- Centralized project management
- Digital platforms

The efficacy of this methodology has been proven during urgent, high-stakes scenarios. For instance, in cases involving orphan drugs for rare diseases, this approach has enabled tech transfers to commercial scale in as little as five months, significantly reducing development timelines and accelerating patient access to innovative medicines.

As the pharmaceutical landscape continues to evolve, with new modalities and increasingly complex therapies emerging, the importance of efficient and reliable tech transfer will only grow. The ability to quickly and safely bring these treatments from development to patient use will be a defining factor in addressing future health crises and improving patient outcomes worldwide.

By optimizing in this critical phase, pharmaceutical companies can accelerate the delivery of life-saving medications and enhance their financial performance, driving growth and innovation across the industry.

The science of tech transfer: Mastering and modeling material behavior

A fundamental understanding of material science is a must-have in the tech transfer process. As drug formulations become increasingly complex and manufacturing processes more nuanced and regulated, the need for precise material characterization has never been more important.

A seemingly simple substance often confounds the tech transfer process in early stages: powder. The behavior of powders during manufacturing processes is actually highly complex and often misunderstood. Particle size, shape, density, and numerous other factors can significantly impact the final product's quality, efficacy, and manufacturability.

To navigate this complexity, cutting-edge tools and techniques have become indispensable in the tech transfer process. These advanced methods not only provide deeper insights into material properties but also serve as a bridge between laboratory-scale development and commercial-scale manufacturing.



Four key tools and techniques are revolutionizing our approach to tech transfer

1

FT4 Powder Rheometer®

This universal powder tester measures powder flow properties and behavior. It provides methodologies for bulk characteristics, dynamic flow, shear, and process analysis. The benefit is a comprehensive understanding of powder behavior, crucial for transferring knowledge about material handling and processing.

2

Shear cell measurement

The shear cell tool provides an understanding of the flow behavior of powders. It offers easy operation and precise, repeatable results. The benefit is gaining quantitative data on powder flowability, essential for scaling up processes and ensuring consistent product quality during tech transfer.

3

Compaction characterization by Heckel analysis

This analysis provides insights into material properties during compaction, including yield pressure, elasticity/plasticity, cohesiveness, and more. The benefit is a deeper understanding of how materials behave under pressure, critical for transferring tablet manufacturing processes or other compaction-based technologies.

4

Compaction simulation

This involves simulating rotary presses and roller compactors. The benefit is the ability to predict and optimize compaction processes without extensive physical trials. This can significantly reduce the time and resources needed during tech transfer, especially when scaling up from lab to production.

The importance of these tools and techniques cannot be overstated. As we face global health challenges that demand rapid development and deployment of new treatments, the ability to swiftly and accurately transfer production processes from lab to full-scale manufacturing can help save lives. Having access and expertise into these modalities for testing becomes a significant advantage in meeting demand as well.

Moreover, as personalized medicine and small-batch production become more prevalent, the need for flexible, well-understood manufacturing processes grows. The insights gained from these advanced material characterization methods allow for more adaptable production strategies, capable of accommodating a wide range of formulations and batch sizes without sacrificing quality or efficiency.

Looking to the future, the integration of these tools with artificial intelligence and machine learning promises even greater advances.

Imagine a system that can predict potential manufacturing issues before they occur, or automatically adjust process parameters to maintain optimal product quality across different scales and equipment.

By leveraging these advanced characterization tools and techniques, we're not just transferring processes — we're translating scientific insights into real-world manufacturing solutions. In doing so, we're paving the way for faster development, more reliable production, and ultimately, better patient outcomes.





Sealed for success: Proven packaging practices in pharma tech transfer

When bringing a new drug to market, packaging often plays an unsung but crucial role. Your clinical results look promising — but does your drug actually look ready to launch?

The packaging journey begins far earlier than many realize — ideally, it should be on your radar from the moment an Investigational New Drug (IND) application is filed. Why?

Because a well-thought-out packaging strategy acts as a shield against many potential pitfalls.

Consider this: Your groundbreaking drug is ready for market, but it degrades quickly

when exposed to light, or it can't withstand the rigors of air transport. These aren't just hypothetical scenarios. They are real challenges that have derailed promising pharmaceuticals. This is where a robust packaging strategy becomes a defense against challenges down the road.

At the heart of this strategy lies stability testing. Your packaging isn't just a container. It is a fortress protecting your product from environmental onslaughts. Rigorous stability studies simulate real-world conditions, pushing your product to its limits. These studies encompass:

- Testing frequency and storage conditions
- Physical, chemical, and bio/micro testing
- Photo stability assessments

A development partner with in-house stability testing capabilities can be invaluable, streamlining the process and catching potential issues early.

But stability is just the opening act. As your product moves through the supply chain, there's a gauntlet of considerations around packaging during shipping.

Extensive shipping studies can help uncover challenges before they're encountered, including:

- Loading and unloading stresses
- Stacking and compression forces
- Vibration during transport
- Impact from handling
- Low-pressure conditions in air transport

There's also the often-misunderstood creative side of packaging—the artwork and labeling. More than aesthetics, this involves a complex balance of regulatory compliance, brand identity, and crucial product information. Key considerations include:

- Brand development and logo design
- Equipment settings and printing feasibility
- Content, format, and naming conventions to ensure regulatory compliance

Get it wrong, and you could face delays or even regulatory rejection. Get it right, and you have a powerful package that achieves product recognition and patient compliance.

Similarly, serialization in the packaging process has become a non-negotiable part of a new launch. It's a data-intensive process that requires early planning and surprisingly intricate IT infrastructure. Key steps include:

- Addressing specialized requirements
- Considering market-specific regulations
- Selecting an EPCIS (Electronic Product Code Information Services) vendor
- Establishing IT requirements and master data management

Assessing your own readiness means asking uncomfortable questions. Could your packaging line handle a sudden surge in demand if demand skyrockets? What if an Emergency Use Authorization creates a sudden need? The key to navigating these challenges is a holistic approach.

Your packaging strategy should be an integral part of your product development, not an afterthought.

It requires collaboration across teams—from R&D to marketing, from supply chain to regulatory affairs.

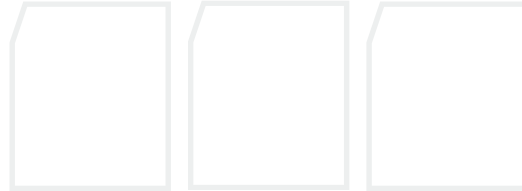
By giving packaging the attention it deserves early in the process, you're protecting your product and setting the stage for a successful launch and beyond.



The value of an expert tech transfer partner

Mastering all aspects of tech transfer is a daunting task. The complexities of economic optimization, material science intricacies, and packaging considerations require a breadth and depth of expertise that is challenging to maintain in-house.

This is where the value of a knowledgeable, experienced CDMO partner becomes clear.



A CDMO partner with a proven track record in a tech transfer can provide:

- 1** Economic insights to streamline processes and maximize ROI
- 2** Cutting-edge scientific tools and expertise for material characterization
- 3** Comprehensive packaging solutions that ensure product integrity and regulatory compliance

Collaborating with a partner that can adeptly navigate tech transfer complexities in your drug development pipeline can accelerate the transformation from clinical success to market reality.

Your innovations and the patients they serve deserve nothing less.

References

1. DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20-33.

16

Ac

Acumen

Find your
missing element
with Thermo
Fisher Scientific.

 [Visit our website](#)

+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com
© 2024 Thermo Fisher Scientific Inc. All rights reserved.
Published 2024