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Blueprint for innovation: Advancing biopharma through technology transfer

Executive summary

Technology transfers (tech transfers) are at the heart of pharmaceutical manufacturing organizations. They're a pivotal component in bringing pharmaceutical products from research and development to initial commercialization and, eventually, to full-scale production. Tech transfers can also be important when outsourcing production to contract manufacturing organizations (CMOs), utilizing alternate production sites to reduce supply risk, and during portfolio transitions such as mergers and acquisitions (M&A).

In recent years, the biopharmaceutical industry has faced many challenges, including those brought by a global pandemic, as well as broader economic, geopolitical, and technological shifts. As life sciences companies continue to enrich pipelines with complex new modalities and seek to improve their response to shifting market trends, tech transfers play an indispensable role.

Suboptimal tech transfers can delay the development or transition of drugs and medical devices, resulting in costly inefficiencies that can slow down entire organizations. Moreover, slow or noncompliant tech transfers may delay product launches or scheduled batches, which may have severe impacts to global supply and product sales. Given their critical nature, executing effective tech transfers is imperative for any life sciences companies looking to increase capacity, optimize manufacturing processes, and maintain compliance with global regulatory bodies.

This paper explores how digitizing technology transfer capabilities can help transform and accelerate this complex set of activities and disciplines. We define five pillars essential for building a robust digital foundation to execute effectively. We'll also share case studies from leading companies in the industry.

Optimizing tech transfers involves fostering collaboration, innovation, and continuous improvement, which allows organizations to improve quality, compliance, development costs, overall cost, and time to commercialization. Because tech transfers rely on so many different functions working in unison, streamlining efforts can help speed up transfers. Furthermore, bolstering tech transfer capabilities can serve as the foundation for an end-to-end digital thread, which may drive benefits beyond just the tech transfer process.

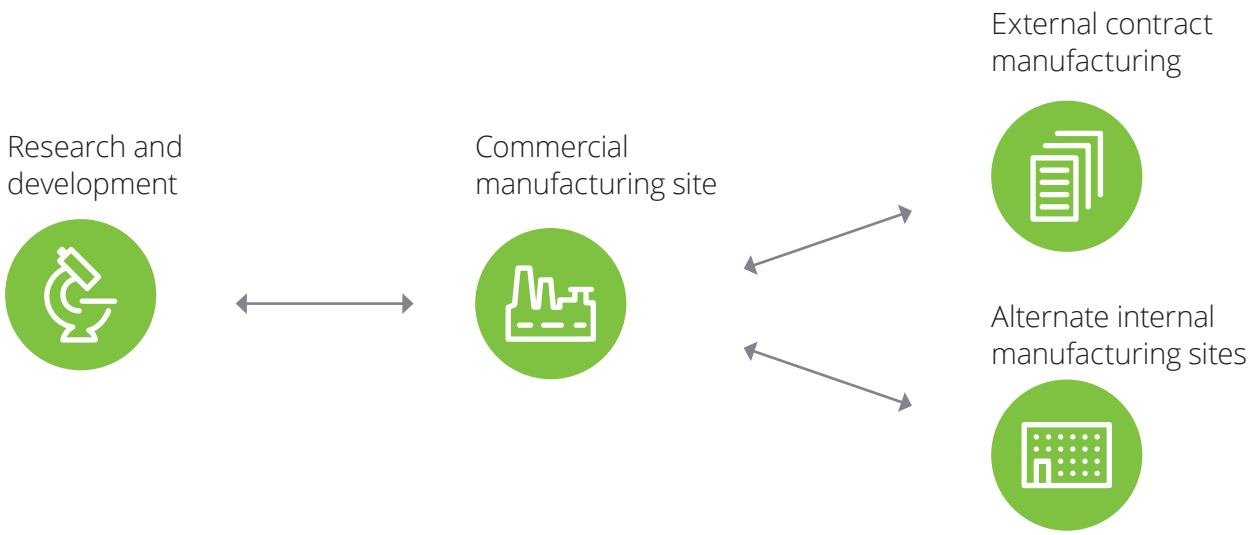
By investing in digital tools to improve upstream enablers within the tech transfer scope, life sciences companies can get a jump-start on digitizing their entire value chain, improve downstream visibility, and position themselves for long-term success and sustainable growth outcomes. In the face of an ever-shifting landscape of patient circumstances and regulatory requirements, prioritizing effective technology transfers will likely become a competitive advantage in the coming decade.

Technology transfer: What it is and why it matters

A tech transfer is the process of transferring documentation, procedures, and methods for manufacturing and analytical processes. It goes from a sending unit (e.g., development) to a receiving unit (e.g., internal or contract manufacturing facility) across drug substance (DS), drug product (DP), and analytical processes. This is how pharmaceutical companies develop and optimize their product portfolios and manage their production capacity across increasingly large global networks.

Tech transfers may be required for various reasons such as scaling processes, switching external manufacturing partners, upgrading existing processes with innovative technology, or replacing aging manufacturing assets.

Biopharmaceutical strategy has shifted from single-molecule blockbuster drugs to multi-molecule specialty drugs, rapidly accelerating new product introductions and shortening product life cycles, thus necessitating more frequent technical transfers. Additionally, broader organizational strategic activities such as asset swaps, network optimization, and M&A or divestitures have also contributed to this increase.



Legend

⟷ Data and knowledge transfer

Within the value chain, research and development and commercialization departments have been able to adapt quicker to the changing market demands, while manufacturing and supply chain experience delays due to equipment, infrastructure, technology, resource, compliance, and scalability constraints. Each year, a large biopharmaceutical company may perform more than 100 technical transfers, with the average cost of a transfer incurring $5 million to $8 million over its lifespan. Leaders who can successfully execute technical transfers as planned have been able to lower the cost of transfers by 30%, making this a priority area to optimize for cost and speed to market.

A shift in strategy from blockbuster to specialty drugs, large-scale to small-scale manufacturing, and single-market to multi-market commercialization can cause numerous and critical challenges across the value chain. The primary challenges are often caused by the inability to coordinate the increasingly complex activities and processes, as well as transformations in the global workforce in which traditional ways of working may no longer meet organizational needs. Ineffective planning and governance, siloed operations and unclear handoffs, misalignment in risk evaluation, challenges with information and knowledge sharing, and additional technical and process complexities have been common themes noted from clients involved in technical transfer.

What we've heard: Typical tech transfer challenges

Ways of working
"Transformations in the global workforce mean that **traditional ways of collaborating no longer reflect the day-to-day experiences** of today's knowledge workers."

Organizational complexities
"We have total 100+ transfers **running in parallel**. Transfer X is delayed. Is there any impact to other transfers?"

Increased emphasis on quality and compliance
"We are expanding our business more globally and that can lead to **different regulations for the same product** when going to market."

Lack of standardized templates
"Knowledge sharing is cumbersome due to a **lack of standard templates** for documents."

Data standardization
"I'm in a **PMO role** and 90% of my time is spent running after functional resources for their data. If only they all kept the **information in one place and in standard format**."

Technical and process complexities
"As processes become more complex, the **details and information** required in a tech transfer **increases**."

Ineffective planning and governance
"Long-term project management can be difficult to execute, and additional **unplanned activities** often increases time to execute."

Siloed operations and unclear handoffs
"Areas of the organization **work independently** and make changes to processes **without sharing the required information**."

Equipment and technology incompatibilities
"Contract Manufacturing Organizations (CMOs) are a big part of our business and tech transfers—their **equipment is often different** causing **additional qualification testing**."

Five areas to target for improved tech transfer outcomes

Organizations have an opportunity to utilize advanced technology to integrate process development, launch, and product life cycle management to help realize cost savings, enhance the transfer process, achieve desired operational goals, and address new challenges derived from changing market strategies. To capitalize on these opportunities, organizations are analyzing technical transfers across five pillars and are looking to leverage next-generation capabilities for insights, engagement, and automation.

Tech transfer pillar	Value levers	Organizational benefits	Early mover examples
Pillar 1: Integrated product data awareness *Integrated digital product data and process models within a connected ecosystem can enable improved visibility to data and usage during earlier stages of product development.*	• Enhanced decision-making • Improved regulatory compliance • Accelerated time to market	Life sciences companies that invest in product data awareness can see many organizational benefits including: 1. Integrated product structure at all levels of the drug product (FP, DP, DS, API etc.) with formulation. 2. Digitized analytical process models (process steps, process actions, process parameters, equipment, etc.). 3. Closed-loop change control process connecting the product and analytical process model. 4. Extensive capabilities where used. This innovation can help effectively increase data availability throughout the end-to-end process allowing for downstream data to be used more productively during earlier stages of product and process development	**Goal:** Enable closed-loop change processes through clear stage-gate processes during tech transfer for product structure, BOMs, jurisdictional control on production batches, etc. **Approach:** An end-to-end digital thread was implemented across clinical and commercial for integrated tech transfers. **Outcome:** Significant benefit to data availability and transfer efficiency/ performance.
Pillar 2: End-to-end planning and execution Optimization of the technical transfer process with next-gen capabilities such as generative project task management to dynamically manage transfers.	• Shorter end-to-end transfer time • Improved forecasting • Improved compliance • Reduced rework	Successful integration of digital project management tools and process streamlining may lead to many organizational benefits via: • Harmonized processes with standard templates across stage-gate milestone tasks and deliverables, enabled via closed-loop workflows for real-time process intelligence insights. • Digital execution use cases, prioritized paperless validation, process robustness analysis, batch record reviews, and regulatory filing preparation. • Fit-for-purpose governance models that scale with the size and duration of portfolio, and eliminate siloed processes across functional areas. • Persona-based life cycles: Right knowledge is readily available for the right people at the right time. • Strategies for managing and controlling changes	**Goal:** Resolve failure to execute tech transfers on time and consistently deal with delays in project timelines. **Approach:** Implemented a digital end-to-end planning solution that could generate project plans, templates, stage gates, and task breakdowns customized based on individual product/process archetypes and required deliverables. **Outcome:** Faster and more efficient tech transfers.
Pillar 3: Portfolio management Utilizing real-time data to generate persona-based contextual information.	• Improved resource forecasting • Reduced product life cycle costs • Reduced FTE costs	Advanced portfolio management tools enable life sciences companies to prioritize projects, allocate resources efficiently, manage risks, and streamline collaboration across departments and geographical locations. With the demand for accelerated development timelines and the need to optimize resource utilization, advanced portfolio management tools provide the framework to enhance productivity, mitigate risks, and maintain competitiveness in the industry.	**Goal:** Improve visibility to their product data for use in strategic decision-making. **Approach:** Organization analyzed and organized product data into visualization dashboards to show the value vs. effort ranking for each product. **Outcome:** Insights to inform divestment strategies leading to more optimal portfolio decision-making.
Pillar 4: Automated submissions authoring Data-driven auto-generation of regulatory submissions artifacts using AI/GenAI-enabled digital tools.	• Improved authoring efficiency • Reduced cost of quality • Faster response to regulatory requirements • Accelerated time to market	Structured content authoring tools allow companies to capitalize off rapidly evolving GenAI capabilities to automate and streamline traditionally labor-intensive processes. As pharmaceutical processes continue to become more digital, this technology will likely have a dramatic impact on any process that relies on templated document generation such as regulatory and CMC submissions, batch record generation, SOP creation, product labeling, clinical trial documentation, etc.	**Goal:** Shorten lead times for regulatory and CMC submissions. **Approach:** Implemented a structured content authoring tool to automate regulatory document authoring. **Outcome:** Streamlined submissions process and increased efficiency of the time spent on CMC document authoring more than 10%.
Pillar 5: Process modeling Use of advanced analytics to simulate engineering processes and gather real-time insights to process performance and compliance.	• Reduced cycle time per project • Reduced material, equipment, and FTE costs • Minimized risks related to tech transfers • Increased percentage of digital tool usage	Life sciences companies can utilize advanced process simulation and optimization tools to help build virtual representations of manufacturing processes and enable scenario testing and optimization without interrupting ongoing production. This can allow for much faster process validation, which has a significant impact on shortening tech transfer times, but it can also lead to more robust and efficient commercialized processes that use outputs from analytical process models to optimize critical process and quality parameters such as yield, potency, and uniformity.	**Goal:** Optimize the tech transfer process and reduce end-to-end lead time for engineering process transfers. **Approach:** Implemented pilots for digital tech transfer process models. **Outcome:** Successfully enabled a 38% reduction in cycle time and reduced cost by more than $2M for one transfer.

Embrace digital transformation in tech transfers

Digitizing tech transfers is about fostering collaboration, innovation, and continuous improvement. By establishing a robust digital foundation across the five pillars of tech transfer, organizations can improve quality, compliance, and time to commercialization. For companies looking to develop their tech transfer processes, it's important to take the following steps to help ensure the readiness and success of their improvement initiatives:

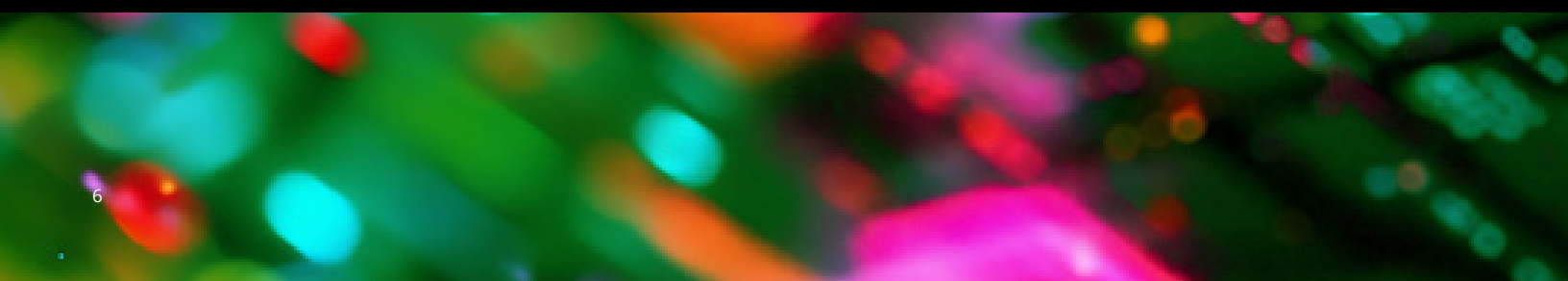
1. Define a global strategy for tech transfers.
Ensuring global organizational alignment around a well-defined vision and objectives will help ensure investments are strategically focused on the most valuable capabilities. Having a strategic plan can also generate excitement among stakeholders and business partners to create a culture of innovation and collaboration.

2. Build data foundations.
To unlock the value in a fully digitized tech transfer process, life sciences companies likely need robust data management capabilities across their value chain to support new digital and analytical processes. Data structuring, accessibility, and accuracy are key to enabling the use of digital tools for process optimization, planning, and reporting.

3. Welcome digital.
Modern innovations in the tech transfer space rely heavily on digital tools and capabilities. Companies should not shy away from investing in digital tools and technologies for their tech transfer processes in the short term as a digital process will likely someday become the standard in pharmaceutical manufacturing.

4. Embrace agility.
Tech transfers are complex and constantly evolving processes that require agile and adaptable processes to quickly react to changing process plans or roadblocks. While standardization is a great goal for increasing organizational efficiency, the tech transfer process should still be fluid enough to accommodate accelerating timelines, new product modalities, and other considerations that could upset highly regimented processes.

5. Explore the art of the possible.
AI and GenAI have the potential to dramatically alter the way many companies conduct their business processes. To help ensure long-term competitiveness in the life sciences marketplace, companies should consider investing in innovative technologies and capabilities to stay ahead of trends in tech transfer process development.



Charting the path forward

Prioritizing effective tech transfers will likely become a key competitive advantage for companies in the coming decade as the industry navigates a constantly evolving landscape of patient circumstances and regulatory requirements. While digitizing tech transfers may seem daunting, Deloitte's Life Sciences professionals have in-depth experience around each of these elements. Our team can help you identify meaningful areas to begin developing industry-leading tech transfer processes.

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